

# AMT LAZMA-2 (BLUETOOTH)

USER MANUAL

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## INTRODUCTION

### DESCRIPTION

The LAZMA-2 is a portable laser microcirculation sensor designed for non-invasive clinical diagnosis of peripheral blood flow. The LAZMA-2 analyses and records the index of blood microcirculation, which is proportional to the product of the number of erythrocytes by the average speed of their movement, using the laser Doppler's shift-based flowmetry method.

The blood microcirculation index is determined at the sensing area in relative units, as a function of time. This registered index allows to assess the dynamics of blood perfusion in the tissue examined. The sensor can additionally measure skin temperatures from 15 to 40°C with an error of  $\pm 20\%$ .

The LAZMA-1 sensor is designed to assess blood microcirculation in the top surface layers of the skin and other biotissues. Possible side effects have not been identified when used accordantly with this manual.

### SPECIFICATIONS

After initiating the sensor, it may take 10 min before the LAZMA-2 will be in operating mode. The sensor provides determination of the index of blood flow microcirculation (perfusion, P) in relative units, using the velocities of erythrocytes moving in vessels in the range of 0.8-4.5 mm/s (at a Doppler signal frequency of 1800-11400 Hz). This parameter should appear around 7-20 relative units with an error range of no more than  $\pm 20\%$ .

The power of continuous laser radiation at the sensor output is no more than 1 mW at a wavelength of 850 nm.

The sensor is powered by an internal 3.7V DC power supply.

A fully charged battery can provide 4 hours of continuous operation.

The sensor operates in conjunction with a laptop or PC. The sensor provides registration and processing of information on the computer. The average service life of the sensor is at least 5 years.

### CONTENTS OF ONE UNIT

The LAZMA-2 is a portable, wearable device. Each unit comes with:

- The LAZMA-2 wearable LDF device
- Straps (2 long Velcro single-straps, 2 short Velcro single-straps)
- Flash drive with operating software, necessary drivers, and user manual



- Bluetooth adapter



- Charger (EU socket)



## SAFETY

The LAZMA-2 may only be used by authorized persons who have read this operating manual and understood the device method of operation and handling.

When operating the LAZMA-2, DO NOT:

- Use a charger with a damaged cable
- Plug in charger with wet hands
- Use a device that has been damaged or has visible defects that threaten its safe operation (further operation is possible after checking by an authorised service operator).
- direct laser radiation directly into the eyes and at reflective surfaces of surrounding objects

When operating the LAZMA-2, you SHOULD:

- Carry out maintenance and repair work by persons with special training
- Carry out maintenance and repair work should only with the charger disconnected
- Keep the devices under normal climatic conditions for at least 4 hours after transportation at low temperatures

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## THE DEVICE

### AMT LAZMA-1

Figures 1 and 2 below shows the AMT LAZMA-2 and its notable features.

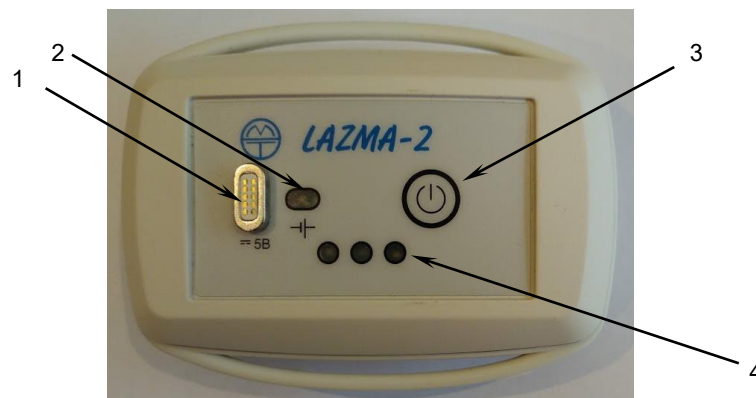


FIGURE 1: AMT LAZMA-2 FRONT SIDE



1 – Charging port

2 – LED indicator of battery charge

- No glow – battery is charged
- “Green” – battery is charging
- “Yellow” – Device needs charging

3 – Power button

4 – Three LEDs indicating device operating mode

**Note:** Pressing the power button (pos. 3) turns on the device and engages the front panel signal LEDs (pos. 4) into a blinking mode. The blinking mode indicates the device is ready to work with the software. After finishing work with the software, pressing the button (pos. 3) turns off the power and the three signal LEDs. It is recommended to turn off the power to save the charging of the internal power supply.



FIGURE 2 AMT LAZMA-2 REAR SIDE

1 – Transceiver window of the LDF sensor.

2 – Transceiver window of the fluorescence spectroscopy sensor.

**Note:** Do not turn off the device power while software is running. Such a disconnection may disrupt the operation of the program. Should this happen, the program will have to be re-initiated.

The body of the AMT LAZMA-2 sensor contains irradiation sources, photodetectors, electronic boards, and an internal power supply. The sensor provides wireless transmission of information to a computer via Bluetooth.

## METHODS OF FIXATION

The devices may be fixed to any area of interest (such as fingers, toes, forearms or legs) using the provided straps (presented in figure 3).

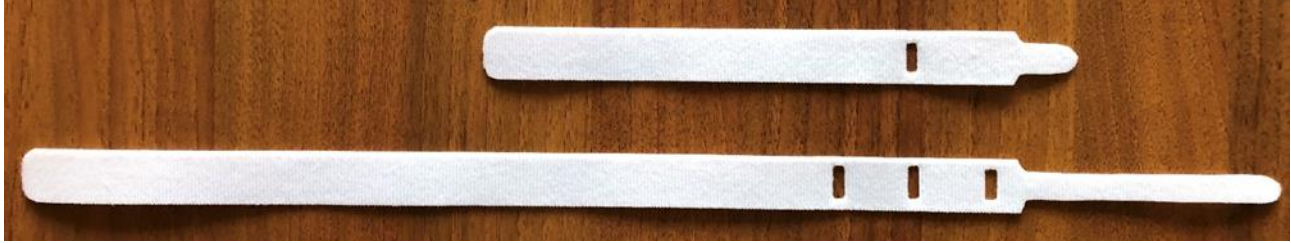


FIGURE 3 STRAPS FOR THE AMT LAZMA-2

The device comes with straps of different lengths. Should a longer length be required, the provided long and short straps can be used together simultaneously.

To effectively fix the LAZMA-2 on the fingers or toes, the short strap is recommended. The “soft” side of the Velcro strap should face the LAZMA-2 device sensor. The narrow end of the strap should then be wrapped around the device and looped back into the “cut-out” as shown in figure 4.



FIGURE 4 SHORT STRAP ATTACHMENT TO DEVICE

The other end of the strap should then be passed through the holder on the other side of the LAZMA-2, allowing for fixation to the region of interest (figure 5). Take care fasten the device securely, but **not to compress the area of interest**, thereby occluding the blood flow.



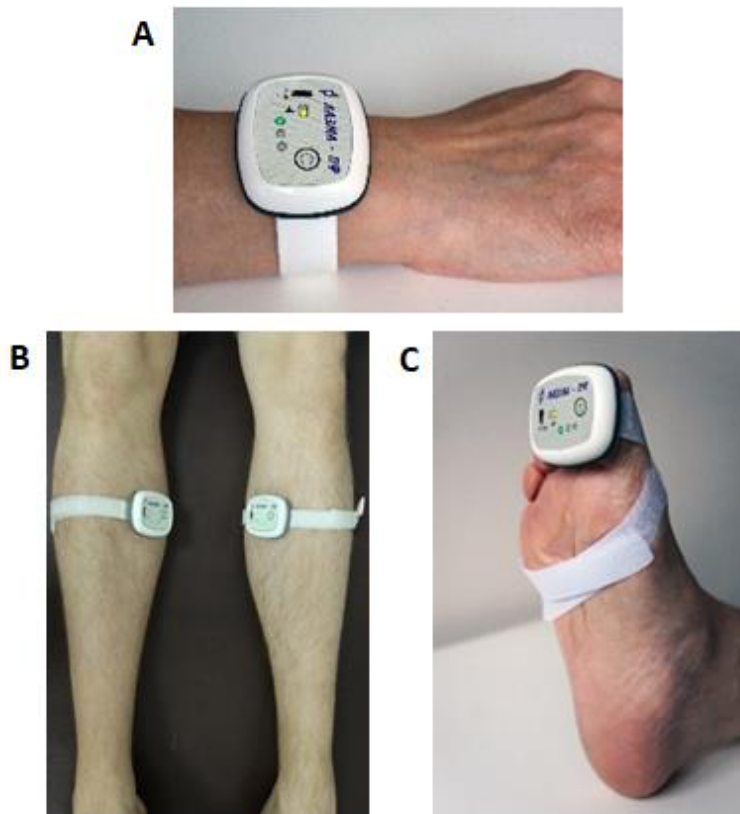
FIGURE 5 SHORT STRAP RECOMMENDED ATTACHMENT STYLE

To use the longer strap for areas of interest such as the forearm or leg, follow a similar methodology as described above, ensuring the narrow portion of the strap runs through all the “cut-outs” as depicted in figure 6. Again it is important to avoid occlusion of the region of interest by over-tightening the straps.



**FIGURE 6 LONG STRAP ATTACHMENT TO DEVICE**

Figure 7 shows the position of sensors during previously conducted research (using the LAZMA-1).



**FIGURE 7 A) WRIST MOUNTED MEASUREMENT, B) SHIN MOUNTING USING LONG STRAPS, C) BIG TOE MOUNTING USING LONG STRAP**

It is also possible to conduct further “custom” fixing methods. We recommend the use of a tubular expendable medical bandage (not provided) for such applications. Example is shown in figure 8.

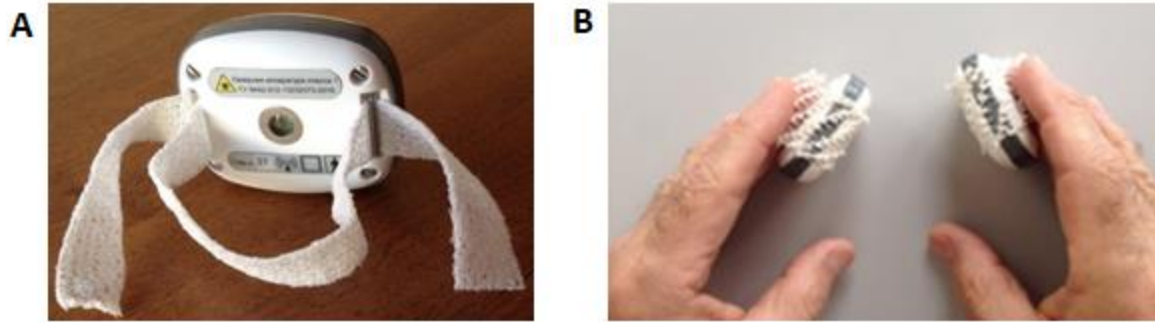


FIGURE 8 A) SUGGESTED CUSTOM FIXING METHOD, B) APPLICATION OF METHOD ON FINGER MEASUREMENTS

It should be noted that the LAZMA-2 uses two sensors (figure 2). As such, it is recommended that the devices should be fixed in a manner that aligns both sensor windows to an area of interest with shared physiological parameters. For example, figure 9 depicts the recommended alignment for measuring data on the distal phalanx of the third finger.



FIGURE 9 EXAMPLE ALIGNMENT OF SENSOR WINDOWS

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## OPERATION

### PREPARATION FOR USE

Take the sensor out of the consumer packaging. Make sure that the charger supplying voltage matches the voltage indicated on the sensor. If the sensor(s) were transported at low temperatures, make sure to keep indoors at room temperature for at least 4 hours.

Prior the use please charge the internal battery by connecting the charger to. The charger is magnetically attached to the socket on the side panel of the device (Figure 1, pos. 1). In this case, the green LED starts flashing up indicating the charging in progress. When the green LED goes off it means that the internal battery is fully charged. With a fully charged battery, the sensor can serve 4 hours of continuous operation. The need for charging is indicated by a flashing yellow LED.

**Note:** It is recommended to regularly charge the sensor batteries before starting work, the charging time is 2-4 hours, the time depends on the battery discharge.



## STERILISATION

The outer surfaces of the sensor are resistant to repeated disinfection with a 3% solution of hydrogen peroxide, with the addition of 0.5% detergent or 1% chloramine solution. The surface in contact with the patient's body is resistant to a treatment cycle consisting of disinfection with 3% formalin or wiping with 3% hydrogen peroxide solution.

## INSTALLATION OF SOFTWARE

The sensor(s) work with the AMT LAZMA-2 Bluetooth LDF software provided on a flash drive with any device(s).

To successfully run the program, the following drivers must be installed (provided on the associated flash drive):

- DB\_Support.exe
- CDM21228\_Setup.exe

Upon installation of drivers, your system must be restarted. Additionally, for Windows 8 and 10 operating systems, the software program should be launched by the administrator.

Software requirements:

- Operating systems: Microsoft Windows
- Processor: Intel Pentium 1.5 GHz (minimum)

**Note:** maximum recommended distance between the sensor(s) and the computer is up to 7 metres in the absence of obstacles (walls, etc.) when using up to 4 devices simultaneously .

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## SOFTWARE

### LAUNCHING SOFTWARE

Prior to launching the software, ensure the Bluetooth adapter(s) are plugged in to USB port(s). The number of adapters must correspond to the number of LAZMA-2 sensors. Up to 4 sensors can be effectively connected. If the number of sensors exceeds the number of USB ports, then we recommend use of a USB port extender (figure 10).

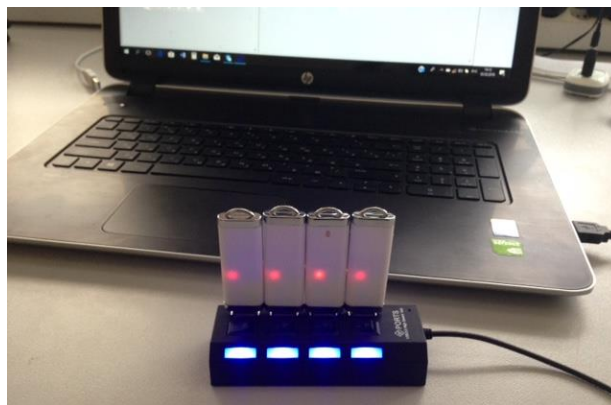


FIGURE 10 EXAMPLE OF 4 SIMULTANEOUSLY CONNECTED DEVICES

Software is launched through the `_LDF_3` executable. This will open a window (figure 11) with available database and list of devices (top right). If 4 adapters are connected correctly, four “check marks” should





appear in the upper right corner of the program (Figure 11). When one sensor or two sensors are in use, the number of "marks" must correspond to the number of sensors connected to the USB port.

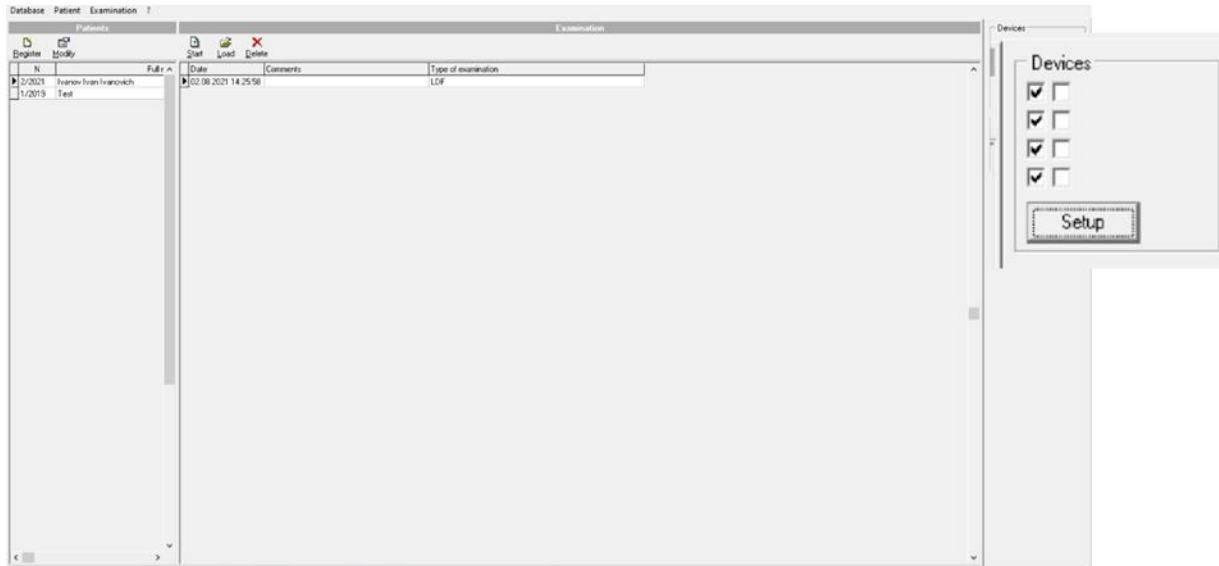


FIGURE 11 LAUNCHED SOFTWARE AND VISIBLE DATABASE (EMPTY)

### DEVICE-TO-SOFTWARE LINKING

**Attention:** When sensors are delivered together with the software, it is not necessary to additionally link them with the software. In this case, go to the "Using the Software" section of this Operation Manual.

To manually link devices to the software, you must perform the following steps. Press the "Setup" button in the top right of the software (under the list of devices). It will launch a new window (figures 12 and 13).

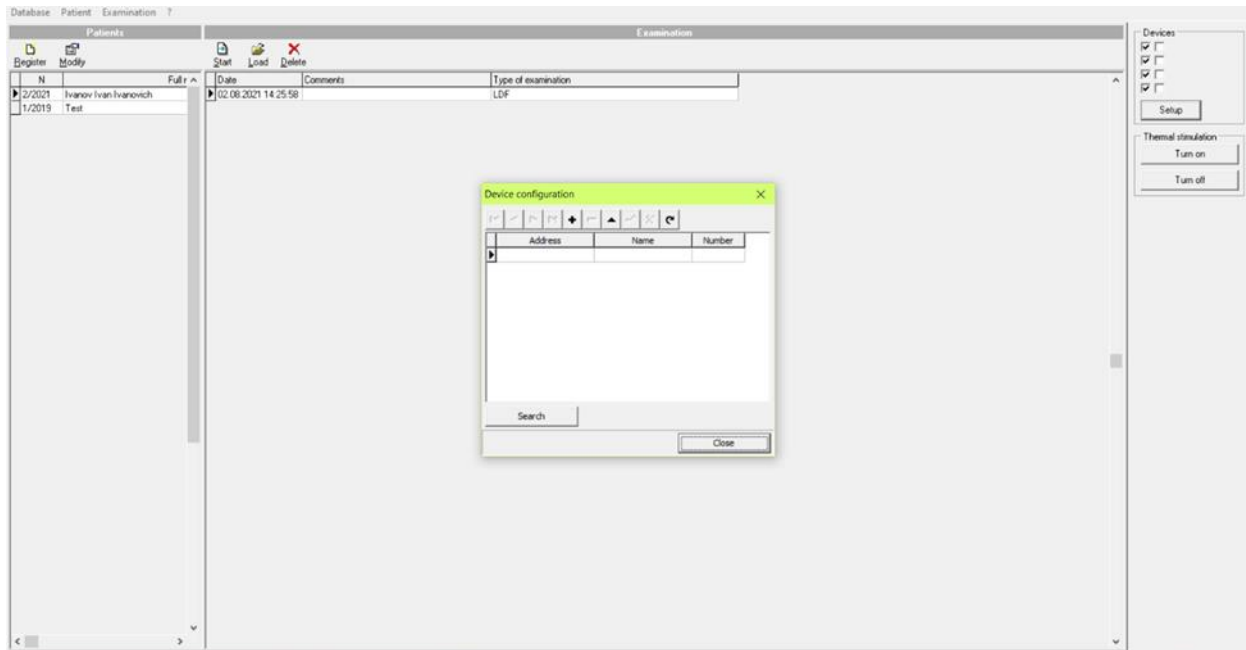


FIGURE 12 SETUP SCREEN

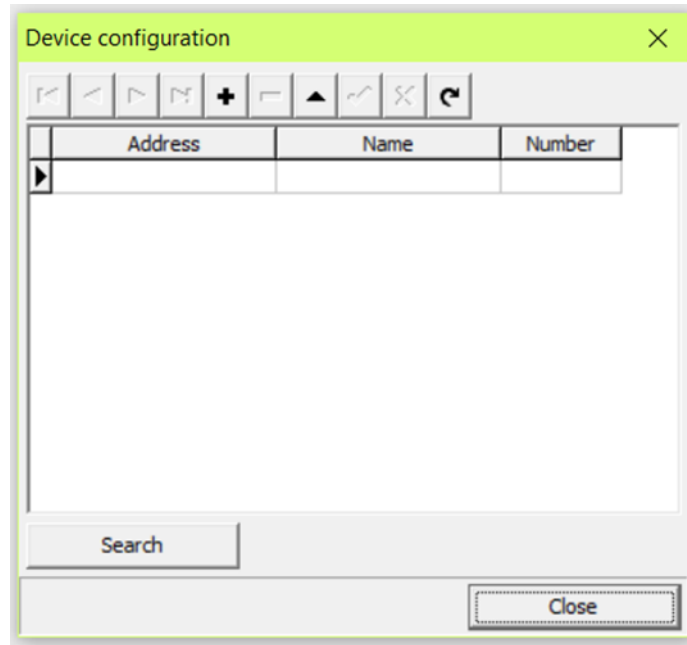


FIGURE 13 DEVICE CONFIGURATION MENU

To connect the devices, it is necessary to press the “search” button. Please note that the devices must be “on” for the software to find them. This will result in a new window appearing called “select device”. Figure 14 shows an example of 1 device being found.

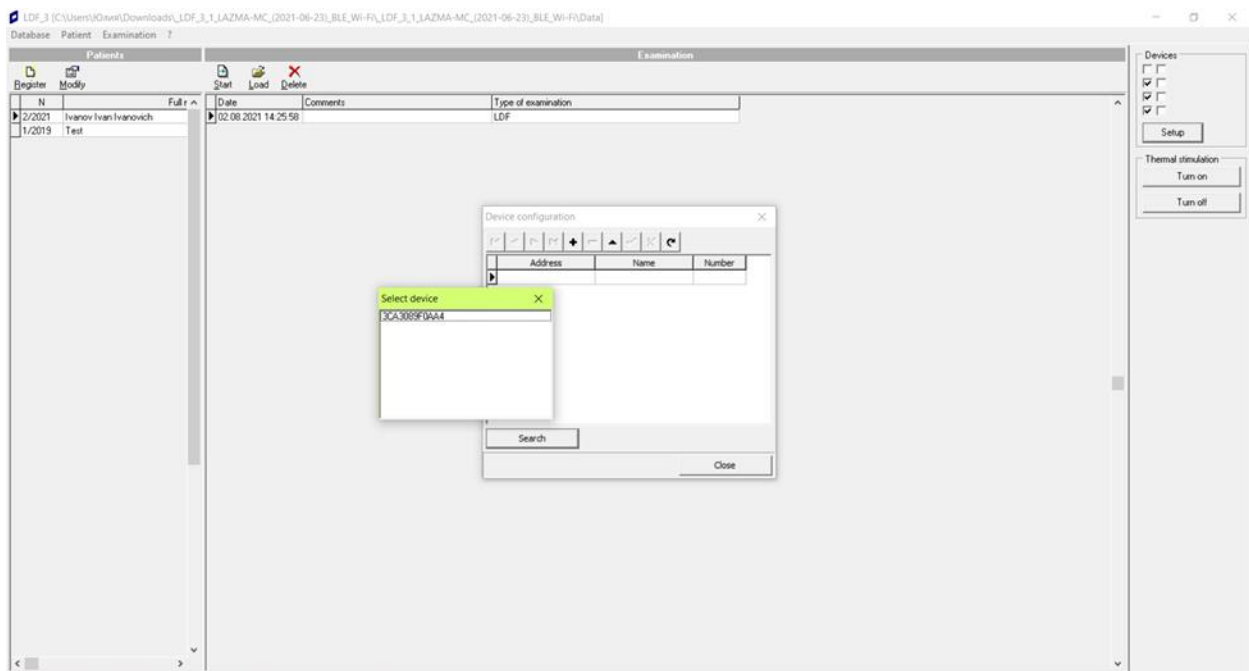


FIGURE 14 SELECT DEVICE WINDOW WITH 1 VISIBLE DEVICE

This window will show the identification numbers for each visible device. These numbers differ from the serial number indicated on the LAZMA-2 back panel.



To select the visible devices, it is necessary to double-click the 12-digit identification number. These selected devices will now appear in the “Device Configuration” menu as shown in figure 15.

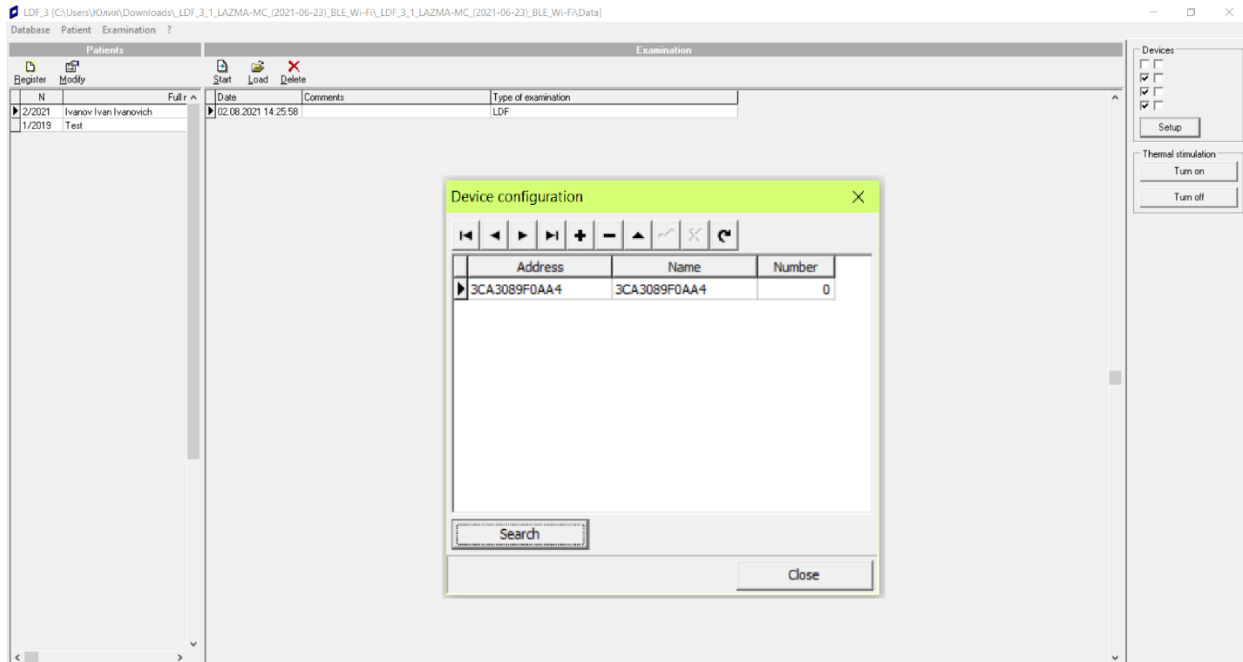


FIGURE 15 DEVICES SELECTED FOR USE

It is then necessary to indicate the “number” for each selected device, to ensure their data is presented and in which order. Figure 16 shows a single device, however up to 4 can be employed.

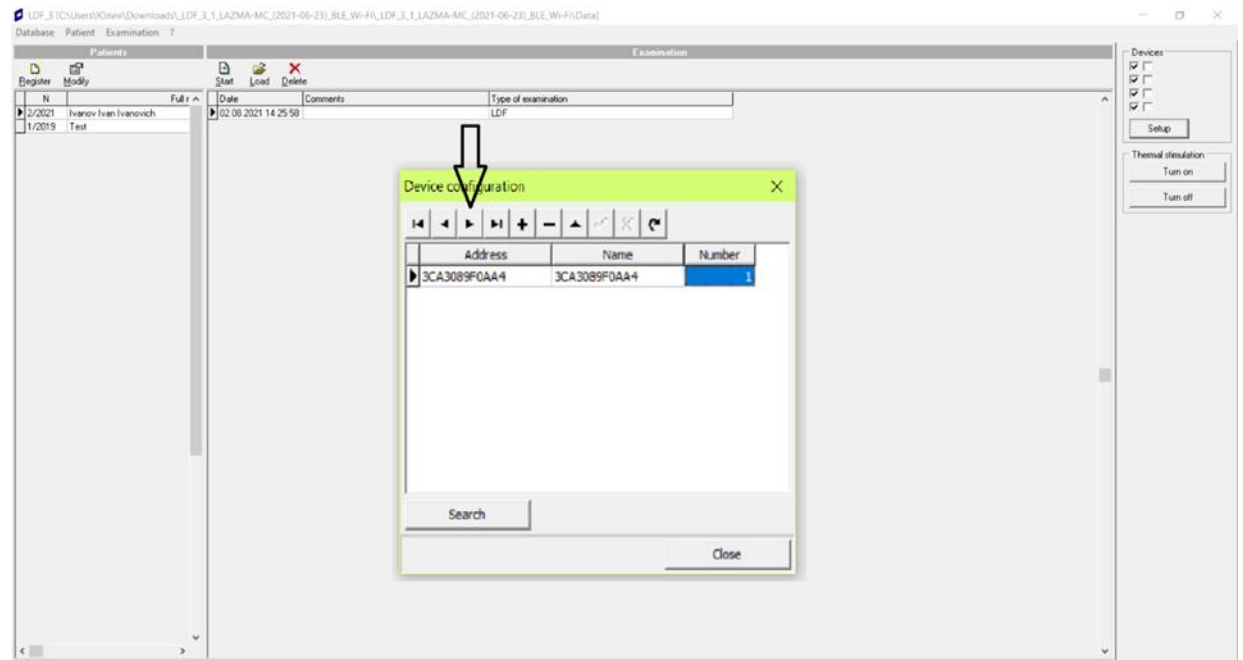


FIGURE 16 FINALISING DEVICE CONNECTION

To complete device pairing, it is necessary to accept changes by clicking on the ► icon for each employed LAZMA-2 device (figure 16). It is also recommended to rename the devices from their identification



numbers to their serial numbers for convenience. Close the device configuration screen to finalise the process.

## USING THE SOFTWARE

Ensure the sensors are located in the areas of interest for your study (for example as shown in figure 7). Launch the software and ensure your devices are correctly labelled in the top right. Register a new patient or study using the “Register” button and continue by pressing “Start” (both seen on figure 11).

You will be taken to a new screen. Ensure that your devices have properly linked. This can be done by checking the top right of the software, where each working device should now have a tick next to it. This process can take several seconds. Select your recording duration (figure 17) and click “start” to begin recording. The following examples are done using one LAZMA-2 device.

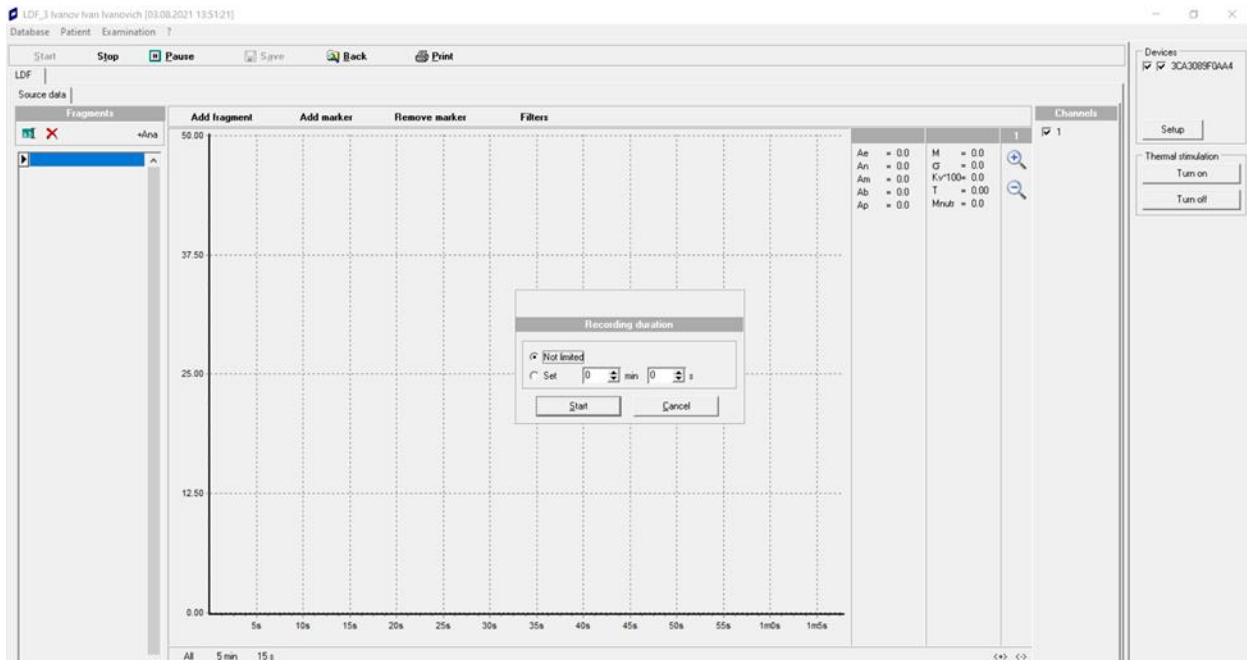


FIGURE 17 DURATION SELECTION

Figure 18 shows the recording screen from one device. Wait until the recording is completed. It will finish automatically after a selected time. If “Not limited” was chosen, it is necessary to manually click the “Stop” button in the top left of the screen. Upon completion of recording **ensure to save it** by clicking the “Save” button.

After the end of the recording, the main indicators are calculated - M,  $\sigma$  and Kv, temperature T °C and amplitudes of blood flow fluctuations (indicators are in the upper right corner of the program window).

**Note:** The traces show data for LDF recording is shown in red, temperature recording in blue and motion recording in black. The blue bar indicates the amplitude of irradiation backscattering, the green bar indicates amplitude of NADH autofluorescence.

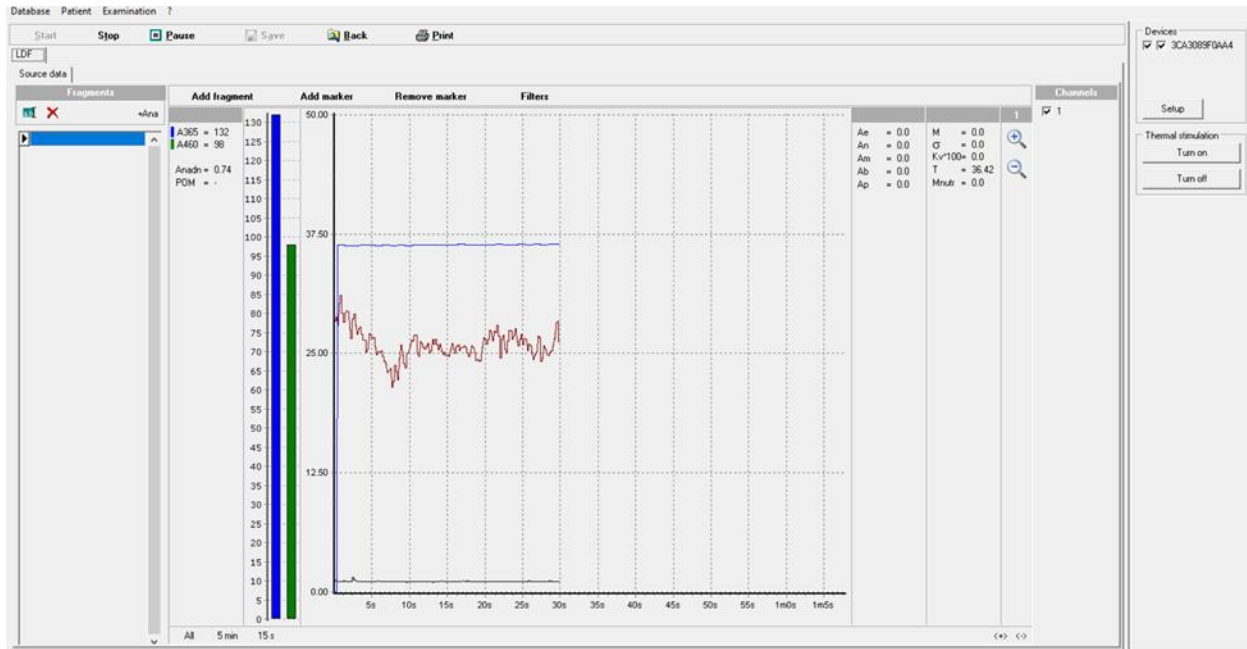


FIGURE 18 RECORDING FROM ONE LAZMA-2 DEVICE

Upon completion and saving of the recording, values for  $M$ ,  $\sigma$  and  $K_v$ , temperature  $T$  °C and amplitudes of blood flow fluctuations are calculated and shown on the right. Additionally, the fluorescence spectroscopy channel data is shown on the left:

A365 – amplitude of backscattering at 365nm source wavelength for excitation of NADH

A460 – amplitude of NADH fluorescence at 460nm

$A_{NADH} = A460/A365$  – relative amplitude of NADH fluorescence, considering the optical features of the tissue area of research

POM – an indicator of oxidative metabolism linking the nutritional component of blood perfusion and the fluorescence amplitude of the coenzyme NADH

If your model of the LAZMA-2 has an integrated thermal stimulation mode, it is also possible to conduct this analysis by click on the "Turn On" option in the "Thermal stimulation" sector during a recording (on the right in the program window - Figure 19).

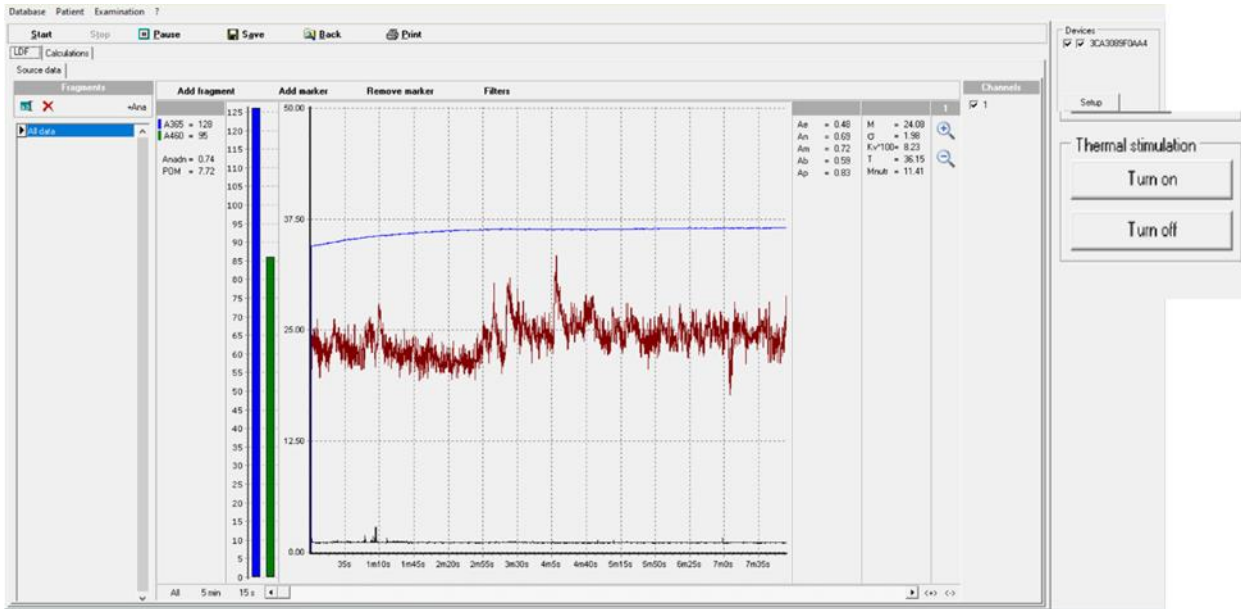


FIGURE 19 THERMAL STIMULATION "TURN ON"

Figure 20 shows an example of a recording with thermal stimulation enabled.

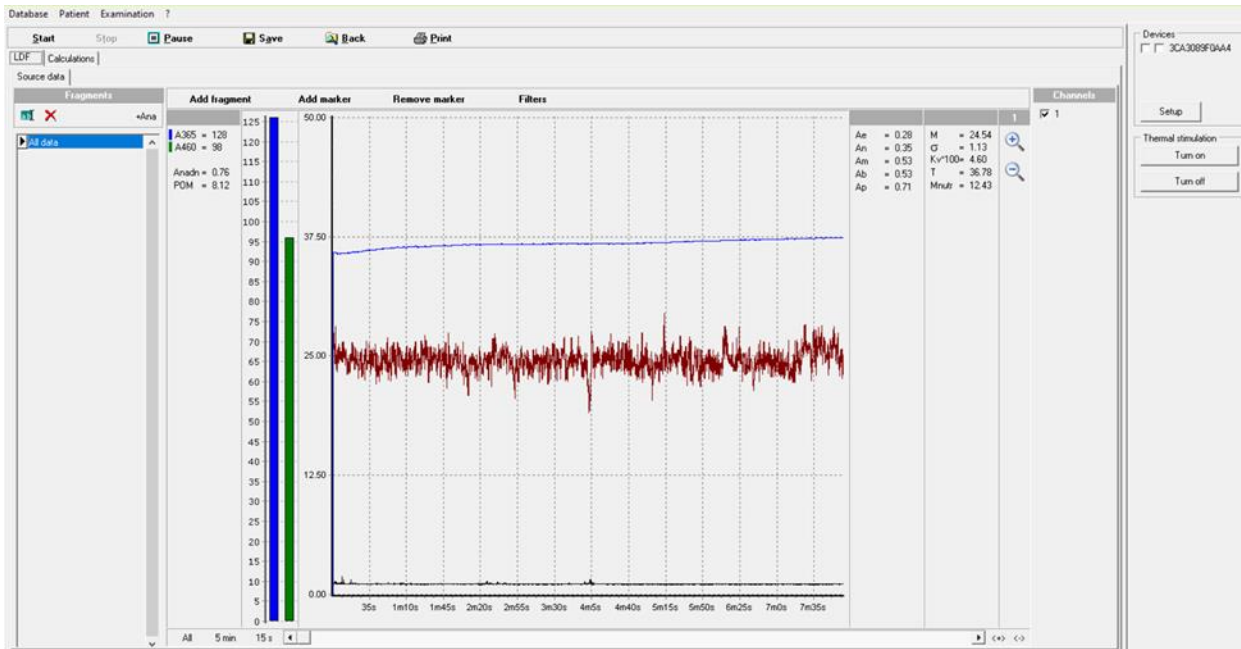


FIGURE 20 THERMA STIMULATION ENABLED RECORDING

In this example, the total recording time is 8 minutes (0-4 min – without thermal stimulation, 4-8 min – with thermal stimulation). With the use of the “Add Fragment” feature, it is possible to break down the recording into two segments shown in figure 21.

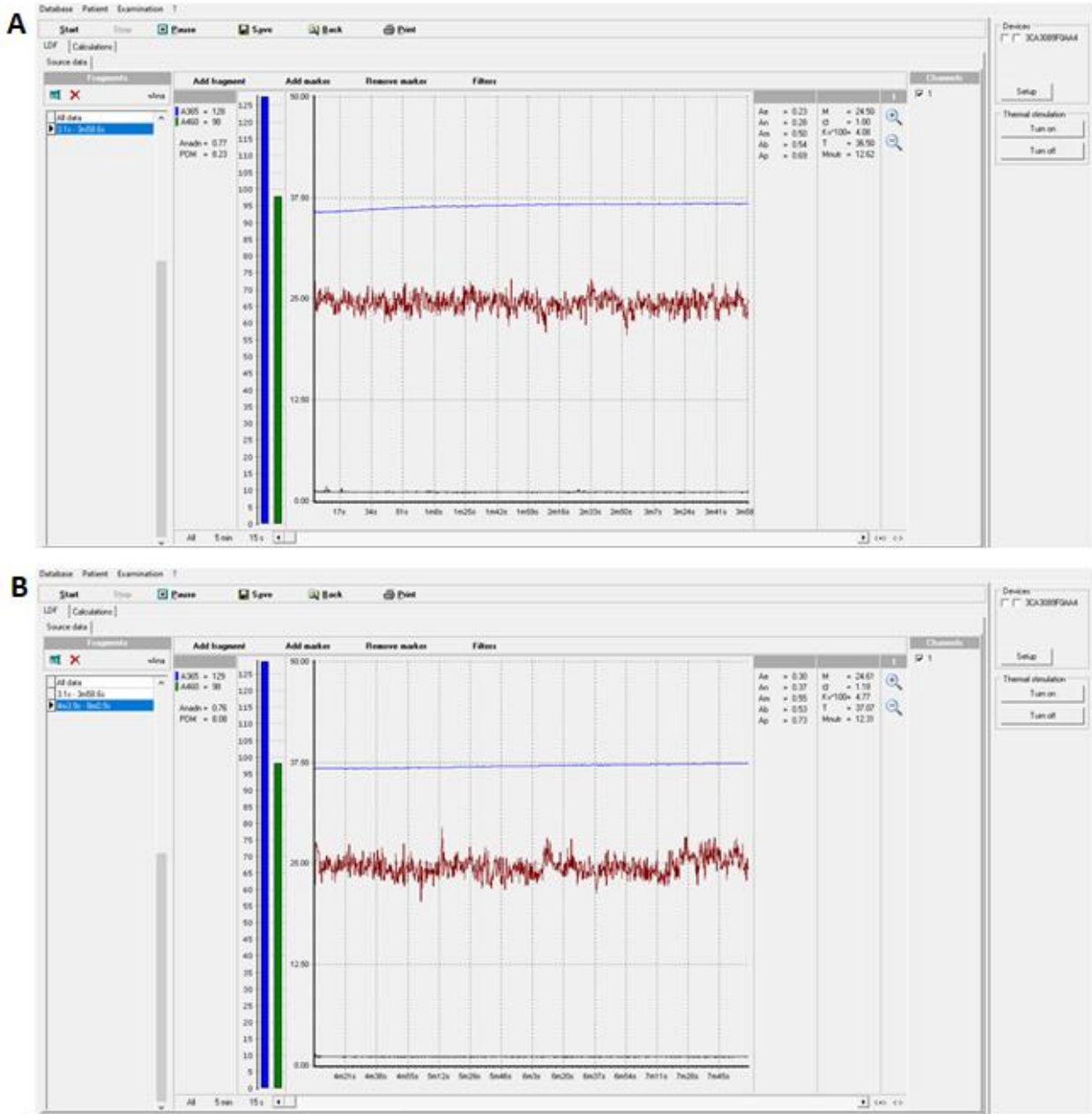


FIGURE 21 THERMAL STIMULATION FRAGMENTS: A) 0-4 MIN, B) 4-8 MIN

The thermal stimulation activates the metabolism. With the help of this test, it is possible to assess the change in the POM index by comparison with the initial state of the tissue of the study area.

If during the LDF recording movement is observed, the sensor reacts and the amplitude of the LDF signals increases. The software provides filtering that allows one to exclude areas associated with artefacts due to motion by clicking on "Filters" button (Figure 22).

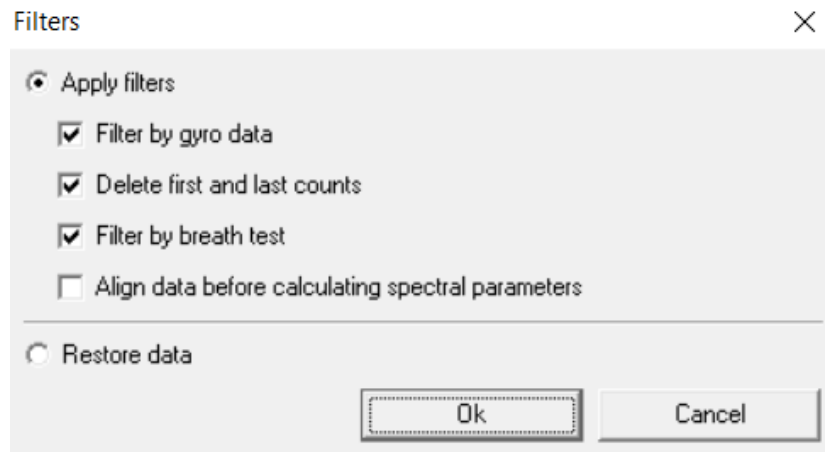


FIGURE 22 COMPLETED RECORDING WITH "FILTERS" WINDOW

From this screen, it is necessary to select all the desired filtration methods. When you check the box for the function "Restore data", the original record will be restored.

After filtration, the correct values of M of the blood microcirculation index and POM are calculated. An example of filtration is depicted in figure 23.





FIGURE 23 A) RECORDING BEFORE FILTRATION, B) RECORDING AFTER FILTRATION

Finally, data from any recording can be exported or the “Calculations” button can be pressed to access the wavelet analysis feature of the software. Figure 24 shows an example wavelet analysis.



FIGURE 24 EXAMPLE WAVELET ANALYSIS

### CONTACT DETAILS

If you require further support with either the hardware or software elements of the AMT LAZMA-2, please contact us via any of the following means.

#### WEBSITE

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