

AMT LAZMA-1 (BLUETOOTH)

USER MANUAL

ASTON MEDICAL TECHNOLOGY LTD.



INTRODUCTION

DESCRIPTION

The LAZMA-1 is a portable laser microcirculation sensor designed for non-invasive clinical diagnosis of peripheral blood flow. The LAZMA-1 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-1 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-1 is a portable, wearable device. Each unit comes with:

- The LAZMA-1 wearable LDF device
- Straps (watch-style wrist strap, long Velcro single-strap, short Velcro single-strap)
- Flash drive with operating software, necessary drivers, and user manual



- Bluetooth adapter



- Charger (EU socket)



SAFETY

The LAZMA-1 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-1, 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-1, 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

THE DEVICE

AMT LAZMA-1

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

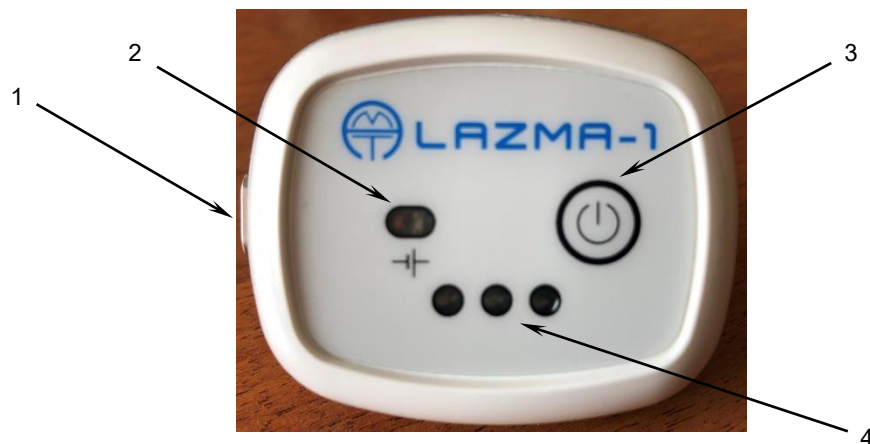


FIGURE 1: AMT LAZMA-1 FRONT SIDE



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-1 REAR SIDE

1 – Transceiver window of the 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-1 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 worn on the wrist using the watch-style strap included (the strap may not match that seen in this manual) as presented in figure 3.



FIGURE 3 WRIST STRAP ON AMT LAZMA-1

To fix the sensor(s) on the shin or on the big toe, it is necessary to replace the strap with one of the Velcro straps (provided). Figure 4 shows the position of the sensor during previously conducted research.

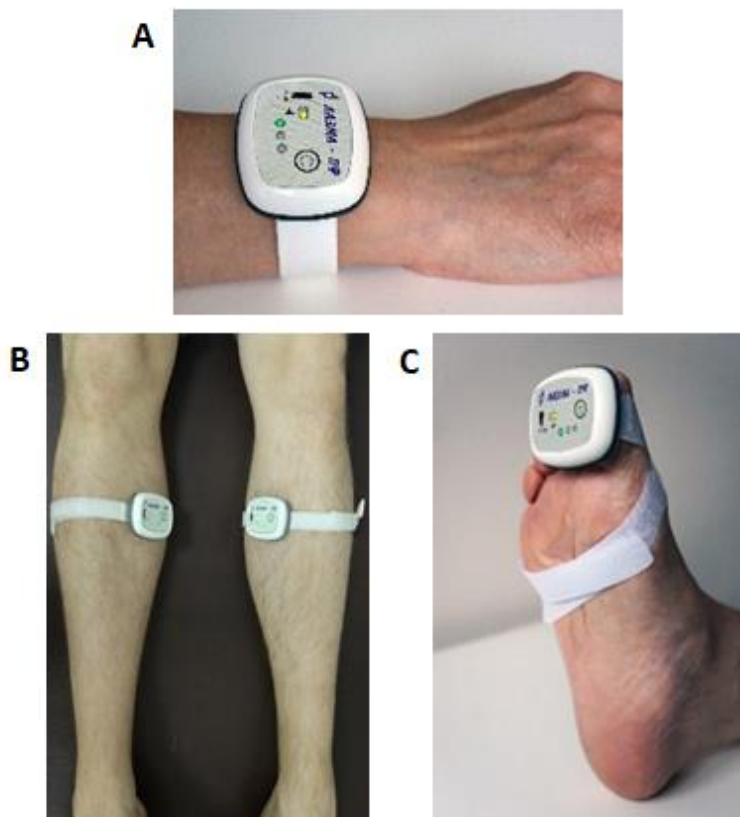


FIGURE 4 A) WRIST MOUNTED MEASUREMENT, B) SHIN MOUNTING USING LONG STRAPS, C) BIG TOE MOUNTING USING LONG STRAP

When mounting the sensor on the finger, it is recommended to use a tubular expendable medical bandage (not provided). Example of application is shown in figure 5.

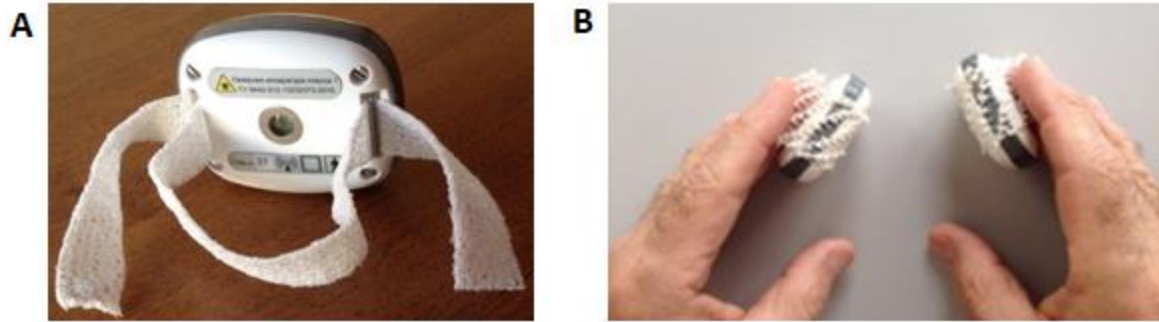


FIGURE 5 A) SUGGESTED CUSTOM FIXING METHOD, B) APPLICATION OF METHOD ON FINGER MEASUREMENTS

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-1 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.

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-1 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 6).

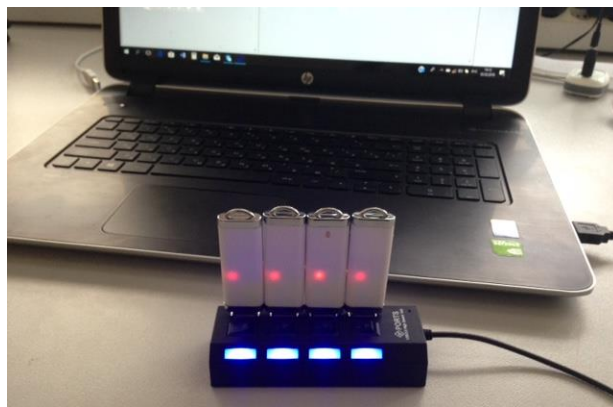


FIGURE 6 EXAMPLE OF 4 SIMULTANEOUSLY CONNECTED DEVICES

Software is launched through the _LDF_3 executable. This will open a window (figure 7) 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 7). 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.

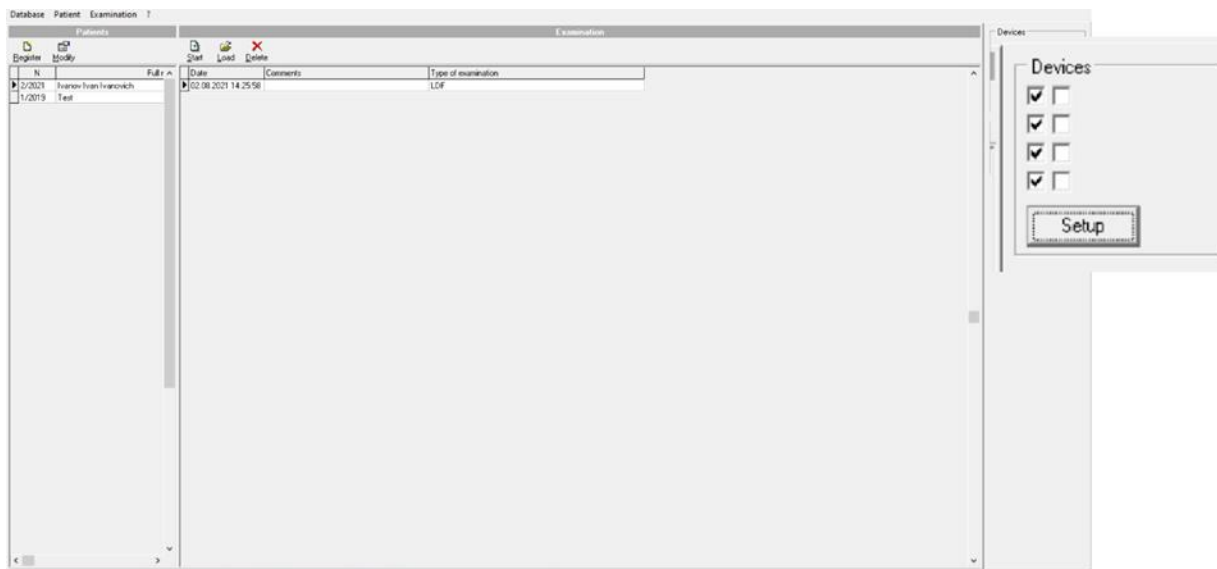


FIGURE 7 LAUNCHED SOFTWARE AND VISIBLE DATABASE (EMPTY)



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 8 and 9).

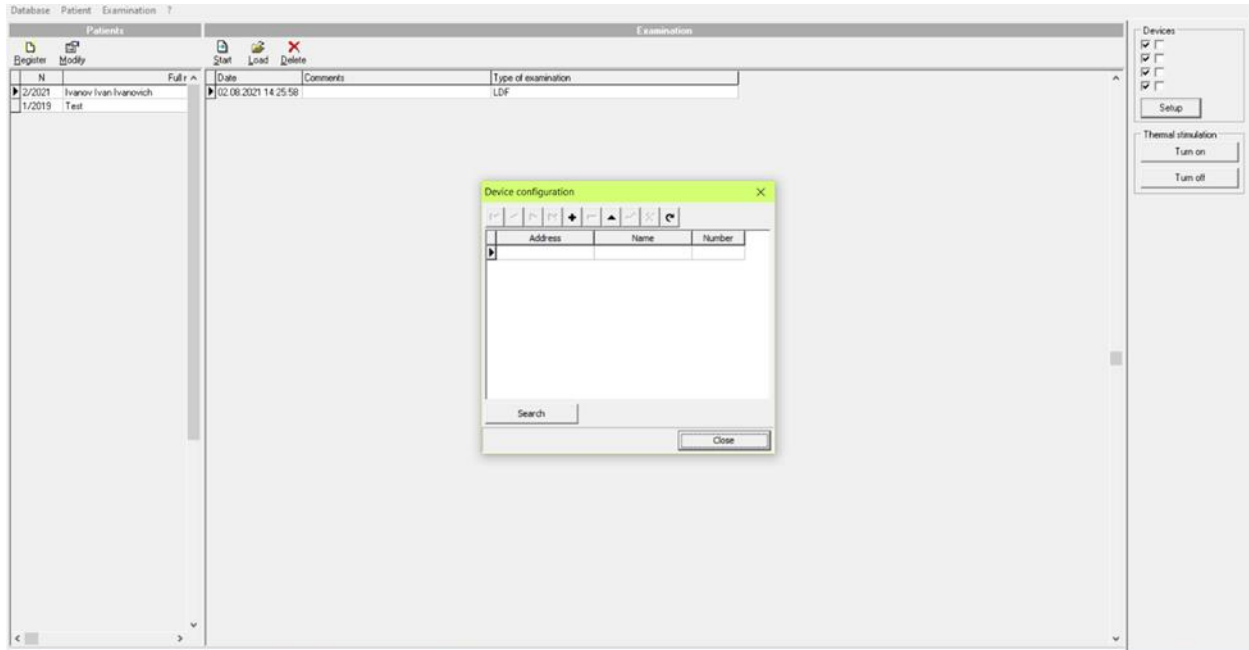


FIGURE 8 SETUP SCREEN

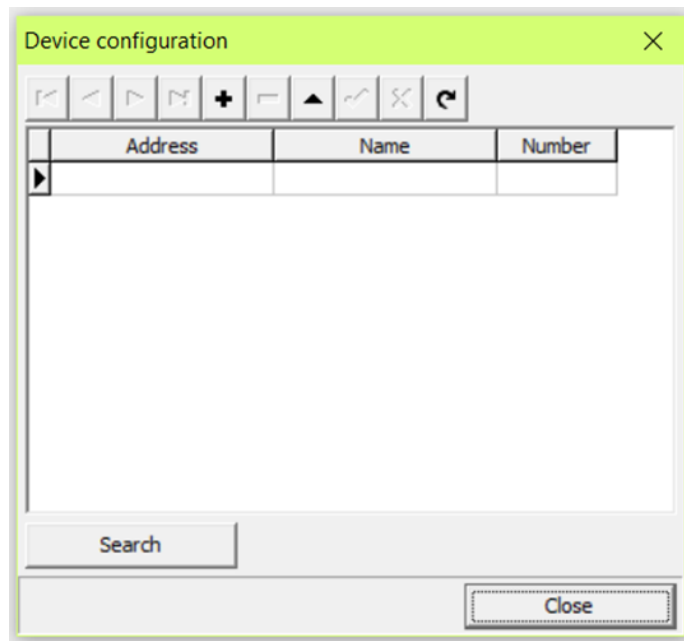


FIGURE 9 DEVICE CONFIGURATION MENU



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 10 shows an example of 1 device being found.

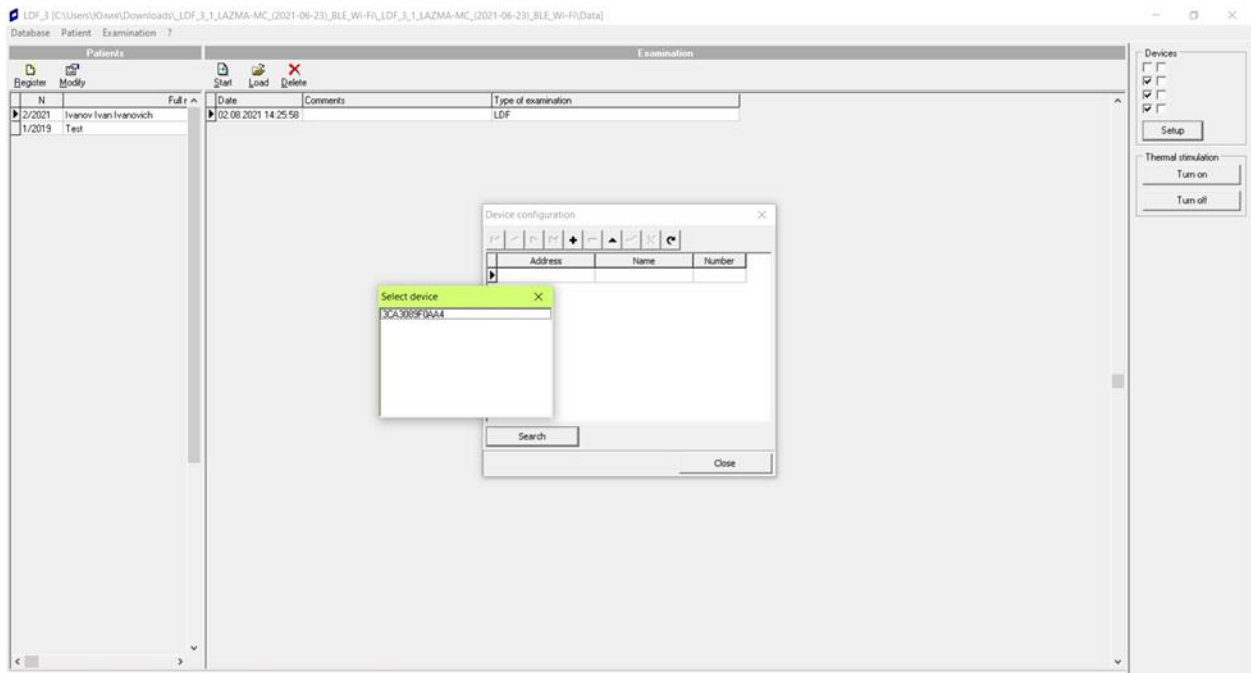


FIGURE 10 SELECT DEVICE WINDOW WITH 1 VISIBLE DEVICE

This window will show the identification numbers for each visible device. These numbers differ from the serial number indicated on the LAZMA-1 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 11.

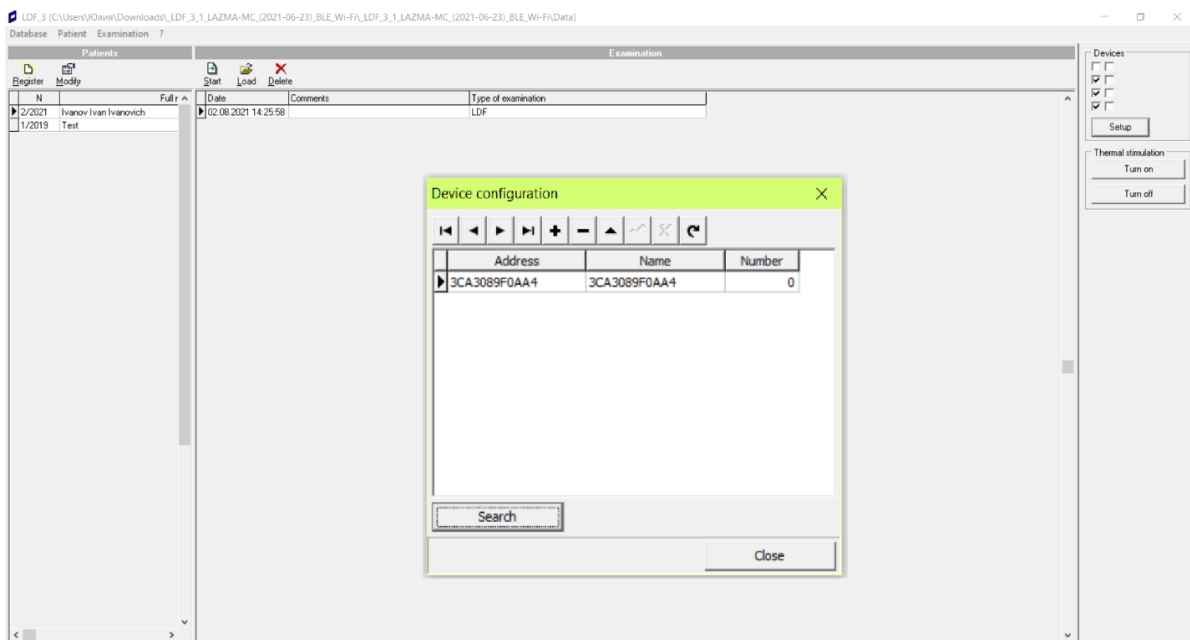


FIGURE 11 DEVICES SELECTED FOR USE



It is then necessary to indicate the “number” for each selected device, to ensure their data is presented and in which order. Figure 12 shows a single device, however up to 4 can be employed.

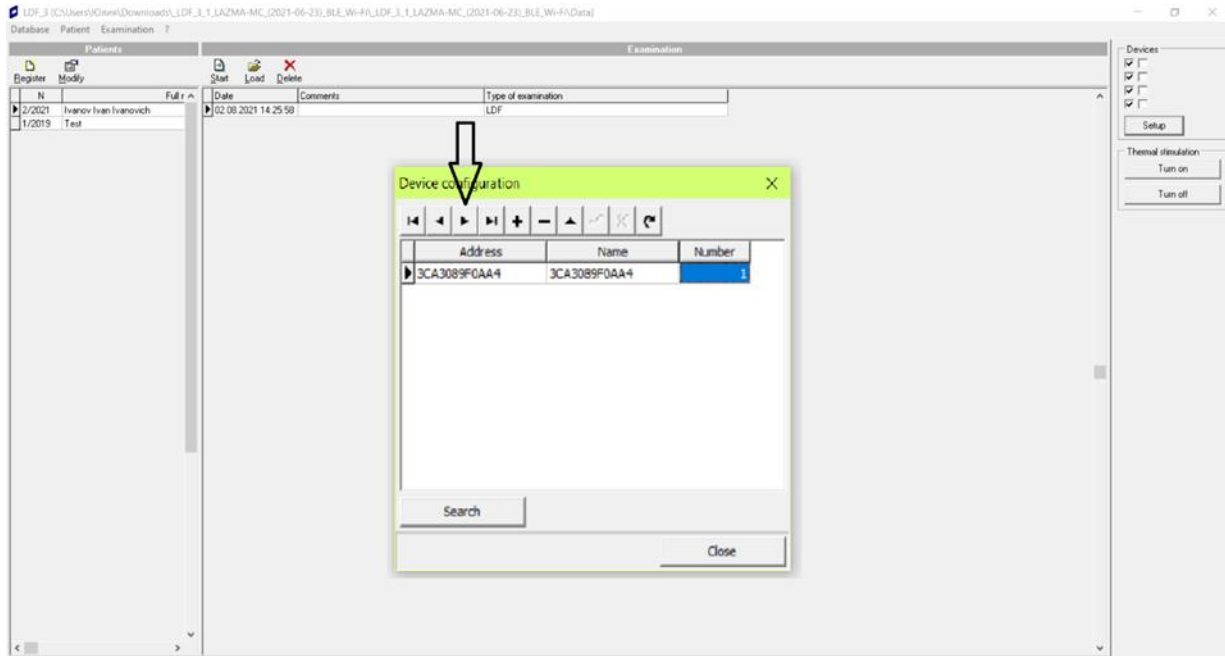


FIGURE 12 FINALISING DEVICE CONNECTION

To complete device pairing, it is necessary to accept changes by clicking on the ► icon for each employed LAZMA-1 device (figure 12). 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 4). 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 7).

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 13) and click start to begin recording (figure 14).

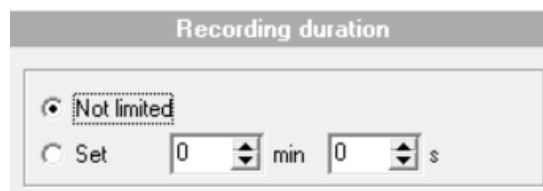


FIGURE 13 DURATION SELECTION

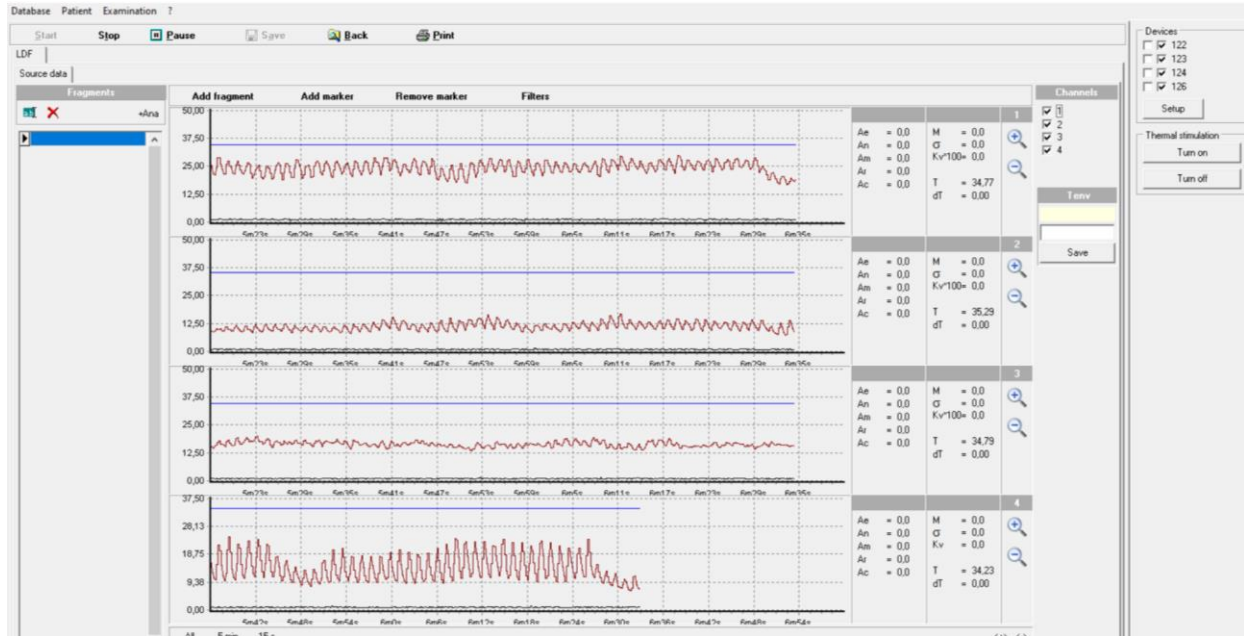


FIGURE 14 RECORDING SCREEN FEATURING 4 DEVICES (CONNECTED STATUS VISIBLE IN TOP RIGHT)

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.

Note: data for LDF recording is shown in red, temperature recording in blue and motion recording in black.

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

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 15).



FIGURE 15 COMPLETED RECORDING WITH "FILTERS" WINDOW

When you check the box for the function "Restore data", the original record will be restored.

After filtration, the correct values M of the blood microcirculation index are calculated. Data from this recording can then be exported or the "Calculations" button can be pressed to access the wavelet analysis feature of the software.

CONTACT DETAILS

If you require further support with either the hardware or software elements of the AMT LAZMA-1, please contact us via any of the following means.

WEBSITE

www.amedtech.co.uk/Contacts

PHONE

+44 7933 22 64 93

POST

5 Selwyn Rd

Birmingham

UK

B16 0SH