User manual

ULTRASONIC DOPPLER UD 48V

Class IIa

CE
0434

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The ultrasonic examination of blood flow by the Doppler method is efficient, accurate, non-invasive, repeatable and inexpensive. It constitutes the basis for the diagnosis of vascular diseases, the results of which direct further diagnostics. It answers unequivocally the question as to whether the patient's complaints are connected to vascular disease. It allows assessment of the area, the extent of pathological lesions and the degree of progression of the disease.

UD48V target applications

UD48V is a Doppler flow meter, designed for the diagnosis of disorders of blood circulation in the peripheral vessels. The 8 MHz probe allows the assessment of blood flow in vessels situated superficially under the skin surface. The reverse flow in UD48Vus disease can be easily detected. Device is efficient in penile vascular mapping by the urologist.
Investigation consists of the assessment of the blood flow waveform, velocity values and indices. The audio Doppler signal is available from built in loudspeaker or headphones.
There are several options to choice including: memory - 10 positions, thermal printer or connection to PC and software for making reports.

The device can be used to perform an examination of the blood flow in the extra-cranial arteries, consisting of the assessment of the blood flow velocity waveform, blood flow direction assessment, the use of the compression tests or percussion of the arteries, and the assessment of the velocity value in carotid arteries.
Based on these parameters we can roughly assess the degree of an artery's stenosis and diagnose its occlusion or generalised atheromatous lesion. It is easier to pull out significant changes in the blood flow in an artery when its stenosis exceeds 50% of artery cross-section and is present in a relatively short segment.
The assessment of the blood flow direction is especially important in vertebral arteries (in steal syndrome), in ophthalmic artery branches (in internal carotid artery occlusion) and in internal and external carotid arteries (in common carotid artery occlusion).
The examination also allows the localisation of embolisms in the large arteries of the lower and upper limbs, such as the femoral, popliteal artery, the crus arteries, and the subclavian, brachial, and ulnar arteries among others. A characteristic "plop" sound is produced by the deflexion of blood from an embolism. The signal fades downstream of the embolism. Localization and assessment of the degree of the vessel's occlusion is based among other things on the analysis of the blood flow velocity curve, the measurement of the mean and maximal flow velocity and measurements of the pulsatility PI and resistance RI indexes.

As far as possible, one should compare vessels on both sides of the patient. Asymmetry of examination results can be a clue to the existence of an early or borderline pathology.
The device can also be used for systolic blood pressure measurements in the arteries of the lower limbs when the pulse in these arteries isn't perceptible by palpation or by means of a stethoscope.
We can also diagnose lower limb thrombosis. In healthy veins the Doppler signal has a booming sound consistent with respiratory function, somewhat reminiscent of the roar of a turbulent sea. No flow is found downstream in the embolism of a recent thrombosis. Upstream, in the proximal part of the veins, the flow is continuous, and unrelated to respiratory rhythm.
Examinations should be performed by a trained person who will not only record the curves of blood flow velocity, carefully monitor and examine the patient's limbs, assess skin temperature and pulse, but will also take into account the thorough medical history of the patient.
The flow meter allows the measurement of the mean and the maximal velocity values and mean velocity envelope. The mean velocity, determined by the zero-crossing method, corresponds to the mean change in the Doppler frequency. This parameter is of great clinical importance, since in the same diameter of the blood vessel it is possible to assess the flow volume and therefore the organ's perfusion. Measurement of the mean value can be less accurate in the case of large lesions in the vessels, causing turbulent flow. The mean velocity measured in such a case is usually smaller than the actual one, because turbulences manifest themselves in flow by components of low frequencies.

Time diagrams of momentary mean velocity are displayed on a liquid crystal display LCD and recorded on recorders' paper, assuming that the angle between the vessel and the ultrasound beam is 60^{o}. The mean value averaged for one heart beat cycle of instantaneous mean flow velocity v_{av}, peak value of mean flow velocity v_{ma} and value of minimum v_{mn} is automatically determined by the micro-computer system. Values are displayed on the screen and printed on paper tape.

Examination method

An ultrasonic probe is placed over the examined blood vessel. The probe or skin at the site of the examination should be covered with ultrasonic gel in such a way as to ensure good acoustic coupling.

The ultrasonic probe is placed over the examined artery at such an angle to the vessel that the acoustic signal is as loud as possible. Usually the angle is between 45^{o} and 60^{o}. It's recommended avoiding simultaneous flow measurement in different vessels. That will result averaging different flow curves. In such a case the probe angle or insonation direction should be changed.

Signals from healthy lower limb arteries usually have three distinguished phases, one after the other: the one louder and of a higher frequency, and two, more silent and of a lower frequency. The first sound is reminiscent of a strong wind blowing; the other two reminiscent of a noise of smaller intensity in those arteries with a smaller degree of occlusion, while in arteries of a greater degree of occlusion (over 50%) the second phase fades and only the first phase, corresponding to heart contraction, is audible. A single-phase signal usually has a high frequency and is similar to wheezing. At, or immediately downstream of, the occlusion, the sound is composite. It consists of high frequencies, corresponding to the acceleration of flooding by occlusion with a superimposed booming tone, usually associated with disturbances of the flow upstream of the occlusion. In carotid arteries where flow resistances are much less than in lower limb arteries, after the first phase usually a continuous Doppler “noise” is audible, corresponding to the continuous flow in the diastolic phase. In atheromatously modified blood vessels signal frequency diminishes, the diastolic phase fades, diminishes or completely fades.

The most important is to listen Doppler sounds – localize vessels and recognize the blood flow character. Vascular Doppler presents the flow direction and allows measurement of the average velocity. The mean velocity (determined by zero-crossing) as the average Doppler frequency change of a blood vessel under examination. The clinical value of this parameter is significant. With a known blood vessel diameter could in fact be assess the flow and as a result the organ perfusion. Measurement of the average value may be less accurate for large, short stenosis in the vessel, causing turbulent flow. Measured in this case, the average velocity is usually less than the actual, since ow frequency components manifest turbulence in the flow. Time diagram (velocity curves), the instantaneous blood velocity are displayed on the LCD screen and may be recorded. The flow value is correct, assuming that the angle between the vessel and the ultrasound beam is 60 °. If the probe is applied at a different angle, a correction of the results should be done. The microprocessor automatically determines the average value of HR, vav average flow velocity, the maximum value of the average velocity vmax and the minimum (diastolic) Vmn displayed on the screen.

UD48V operation

The device is powered from an internal rechargeable battery. The probe is to be connected to plug-in socket on the back panel marked respective transducer. As the halves of CW probe crystals are symmetrical it's not important the order of connection.
By means of the arrows up and down push buttons, the level of audio volume of the Doppler signal is adjusted. Upon starting, the device is automatically set to the middle volume range. The unpleasant clicks and noises, which can occur by the application of gel and violent probe movements, are automatically reduced.
In absence of Doppler signal for more than a five minutes, the device will automatically switch off, thereby saving the battery. When a battery is fully discharged UD48V will be automatically switched off and switching it on again will be impossible. The battery should then be re-charged.
The device is portable, equipped with handle for carrying the unit. UD48V is easy to use. The function keys on the screen are described further. In both on-line and freezing mode user can change registered velocity scale (respectively 20, 40, 60, 80, 120, 180, 240 cm/s), presentation form (flow towards and reverse the probe - A-B; A; B; AB) and time base sweep time. Time diagrams of momentary bi-directional velocity curves and calculated values are displayed on a liquid crystal display LCD and may printed on thermal printer. The frozen on LCD curves can be reviewed (24 seconds) adjusted in scale and display mode, stored or printed. The real time clock adds the recordings stamp.
After switching on the device is ready to work with last used setting.

Back panel description:

-  Probe socket (marked with MHz for transducers)

 - charger - power supply input 2,1/5,5mm 12V DC 400mA

-  communication port to PC

On the back of the device in the upper left corner are the transducers sockets markad respective of 4 and 8 MHz.

In the upper-right corner of a button 0/I to switch device on and to enter the menu level settings.

Below is the mini USB input for connecting to your computer PC.

In the lower right corner of the socket for connecting the charger with led, which lights up in green as the device is connected to the mains.

In the middle located is the speaker.

UD 48V turns on by pressing the silver button 0/I. Long (about 30 seconds) press of the same button until the image disappears from the display means emergency turning off the device. When the device is turned on it automatically sets in the mid range audio volume and is ready to work. The Doppler signal volume can be set using the buttons up/down in the shape of the triangular arrows.

Operations and controls

The operating modes **-** the instrument has four basic modes of operation:

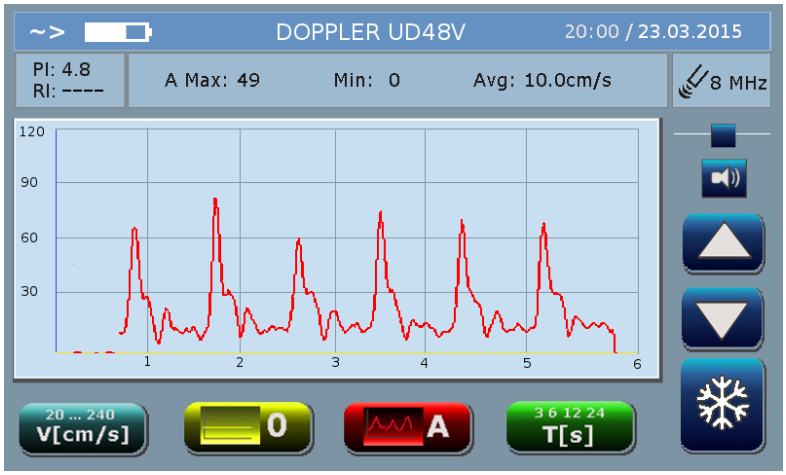
MEASUREMENT, REVIEW, ARCHIVE, SETTINGS,

On the touch screen partson the bottom and on the right side contain the function symbols that are at the same time buttons. Part of the screen with the displayed curves and the results are not intended for the touching (to avoid gel on diagnostic part of the

display). Buttons for functions related to the choice of serve to activate these features, and after making a selection (up/down arrows) to confirm your selection.

MEASUREMENT

It is available immediately after you start the device.



By entering the measurements just put the gel on the probe begin to localise the blood vessel respectively by Doppler sound and the signal flow display.

It's operating mode, in which the flow presentation may be modified using keyboard buttons;

you can change the following items

- 

the scale of the velocity registered (20, 40, 60, 80, 120, 180, 240 cm/s).

When you start the instrument the scale is set automatically, but pressing V will be modified and active manual mode

-what gives you the ability to manually set the velocity scale: each press of the button changes it. If you did not select a specific scale setting button is automatically checked for adequate signal. Another press of the button changes the scale range in the subsequent steps, up to a maximum, the scale automatically back and forth following ranges.

- 

-the position of the zero line (consecutive press move one fourth of the range).

- 

-choice of presentation of the direction of the blood flow (the corresponding towards probe A, both independently A/B, one bi-directional process A-B, same outflow B))

-the scale of the time base of registered waveforms: 6sek, 12, 18, 24,30

Additionally

-   – the triangular arrows "up-down" controls audio volume of the Doppler signal during the measurement, movements in other modes.


-pressing the speaker button mute the sound (symbol changes to the color yellow)


Let the speaker mute

REVIEW


-level of equipment available when you first press frozen (indicated by a change in color)


last recorded data frozen (and remembered always with a length of 30 seconds). Then:

-buttons velocity scale, time and form of presentation are working the same way as in the mode of measurement.

-The triangular arrows up-down allow you to rewind a registered curve (if you choose a shorter segment presentation then 30 seconds)

ARCHIVE

 -the entrance to the next level of the menu when you press the snowflakes again.

In this mode, the buttons appear:

 - Record data to the cache memory

 - Option to read from memory.

Triangular arrows up-down select process to read and press "M" again. We get to the level of browsing, which will temporarily record the data.

Press the "snowflakes" back to the level of the ARCHIVE, pressing the "snowflakes" go back to the MEASUREMENT level where we can continue the diagnose.

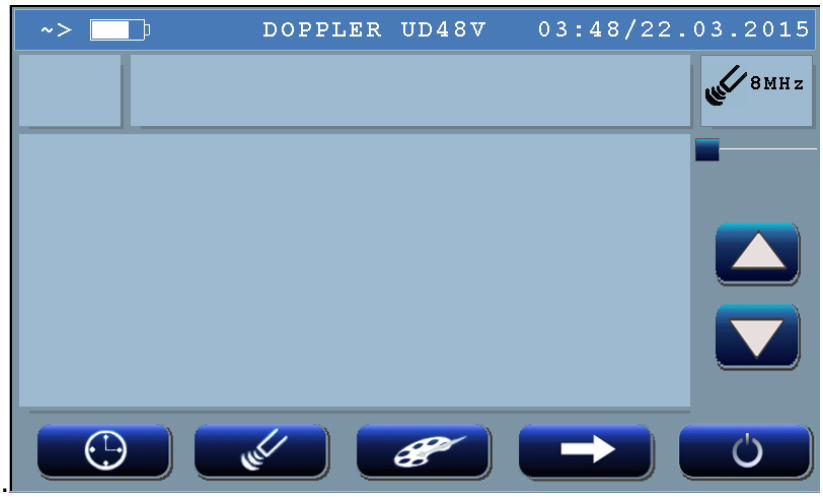
 - Printing. Be sure to use thermal paper recommended by the manufacturer

 - Delete the entries from memory-when you press the "Recycle Bin" on the screen of the instrument appear memorized data course, date and time of registration. Choose between runs we make triangular arrows "top-down". Delete the selected course to confirm the "Recycle Bin". If you don't want to delete anything we use "snowflake" to reach the MEASUREMENT mode.

SETTINGS

Activated by short pressing the silver button 0/1, located on the back of the device,

Screeen in settings mode



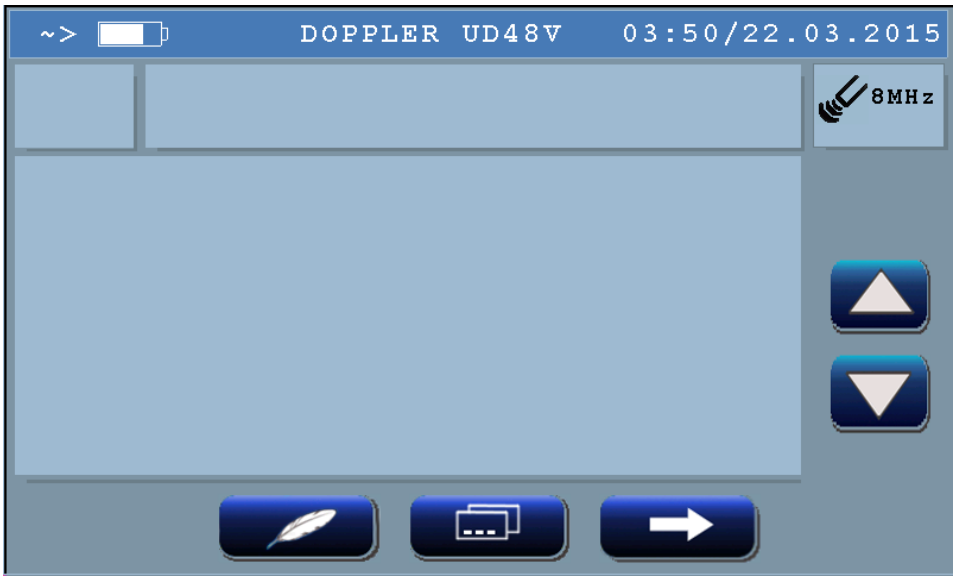
 -clock-press "clock" you can set the time and date time: set the triangular arrows up-down, after setting the hour "clock" go to minutes and set them also buttons up-down. The "clock" go to date and year settings buttons up-down and continue to the month and day and accept the "clock".

 -choice of transducer

-press "probe" appears a selection of 8 MHz and 4 MHz which select buttons "triangular arrows up-down" and accept it by pressing "probe". In options with PPG this transducer is also to be choose.

In the upper right corner displays probe type which we will use.

 -the option, after you press we can choose

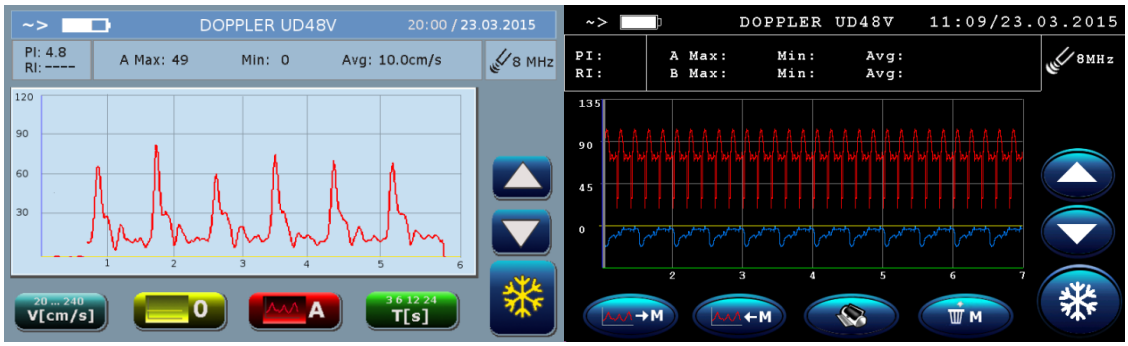


 - pen button change version of the language (Polish, English)

 -the color of the screen

-press the "color screen" appears to us a selection of "Theme" Black "or" Blue Theme" by selecting the button "triangular arrows up-down" button again to confirm the" color of the screen"

Below available colors (palette)



 - back to the level of MEASUREMENT

 - **switching device OFF**

PRINTER

- up-down arrow and choose data, which we would like to print, adjust if required and

- to freeze the selected data

 ,

- Press “printer” that corresponds to the function "print". After you print the data corresponding to the presentation on the screen recorder automatically stops and you can peel off the paper. It is not possible to interrupt earlier. In the absence of paper while trying to register a message appears on the LCD screen.

HOW to EXAMINE

Doppler blood flow Study is an effective, non-invasive, repetitive and cheap. It is the basis for the diagnosis of vascular diseases, and its outcome provide further diagnosis and treatment. This study gives a clear answer to the question: is the patient's ailments are associated with a disease of the blood vessels. It also allows you to assess the site and the sheer size of the lesion and the degree of progress of the disease. When carrying out the test you should always compare the two limbs. The asymmetry results may be an indication of the existence of early or organic pathology.

Ultrasonic probe position over the blood vessel. The probe or skin in the place of study should be moistened with ultrasound gel, liberally so as to ensure good contact. More, it is advisable to use excessive than too small amount of gel. You should beware of unnecessary pressure with probes on the surface of the patient's skin in order to avoid unnecessary unpleasant sensations and do not interfere with the flow in the diagnosed the blood vessels. In addition, it should be remembered that in the few cases where ultrasound gel can cause allergic reaction of the skin, you should warn the

patient. In the case of the risk of contact with damaged skin should apply a sterile protective on the probe.

Ultrasonic probe shall be positioned over the artery under such an angle to the vessel that an acoustic signal was the loudest. Typically, this angle is contained between 45° and 60°. You have to remember that scales and digital value determined velocities are calculated assuming the Doppler angle of 60 °. a deviation of the order of 7 degrees from this angle causes an error close to 10%. If for any reason there is a need to test flow for other than 60º.it should be necessarily taken into account when interpreting the results. As a rule, the scale and size of recorded digital values should be treated as auxiliary indicators rather than as objectively measured values. The most important are: the nature of the movement, its dynamics, sounds and phases, the relationships between the different parts within the heart cycle

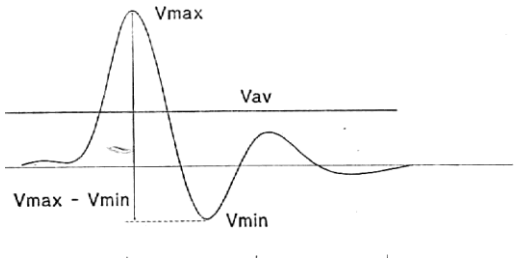
Signals from healthy arteries of the lower limbs are usually three distinguishable, occurring one after the other phases: louder with a higher frequency and two quieter the frequency lower. The first sound reminiscent of the blast and another two smaller noise intensity. In the arteries narrowed to a small extent, the second phase disappears while in the large arteries occluded over > 50%, we hear only the first phase corresponding to the systole of the heart. Single-phase signal is typically high frequency hissing recalled. In the place of or just below the occlusion the sound is changed. It consists of a high frequency corresponding to the acceleration of the flow by constricting with low vibrating tone, usually associated with impaired flow aortic stenosis. In the carotid arteries, which are much smaller than the flow resistance in the arteries of the legs, after the first phase of the hearing normally continuous Doppler "noise" which corresponds to a continuous flow of diastole phase. In the blood changes. The device can also be used for the measurement of systolic pressure in the arteries of the lower limbs, when heart rate in these arteries is not found palpated or using a stethoscope. Most such research is used to determine, in addition to the systolic pressure in the arteries of the hands and feet, the pressure indicator ABI, (ankle/brachial index) that correlates very well with the degree of stenosis of the artery. Location and evaluation of the degree of stenosis of the vessel is based. on the analysis of the velocity curve of blood flow measurements flow velocity envelope’s average and maximum and flow measurements, pulse index PI and RI resistance.

Automatically calculated values are displayed in the upper part of the screen average and maximum velocities and:

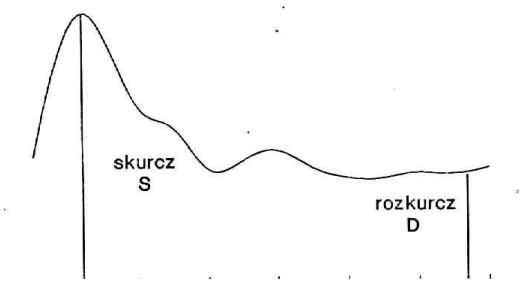
PI – pulsatility index

RI – resistance index

$$PI = \frac{V_{\max} - V_{\min}}{V_{av}} = \frac{f_{d\max} - f_{d\min}}{f_{av}}$$



$$RI = \frac{S - D}{S}$$



You can also test the location of blockages in the large arteries of the lower extremities and upper, such as:. femoral, popliteal arteries, Subclavian brachial Ulna and others. Reflection of the blood from the congestion causes a distinctive sounding "plop". Below the congestion tone fades. We can also recognize the thrombosis of the lower limbs. In healthy veins of the Doppler signal has a "buzzing" sound that is reminiscent of the sound of the sea heaving must sometimes compatible with respiratory activity. In a fresh flow of non-thrombosis blood clot below. Above, in the part of the veins, flow is constant, independent of the respiratory rhythm.

Optional PPG PROBE

It can be connected to a apparatus having such rear PPG probe connector next to the speaker. The performance of the housing of the socket is the proper positioning of the connector when connecting the probe. As soon as the probe choose is the PPG in the menu option the part of Doppler is no longer active. Then on the screen we see 12 or 96 seconds. This allows to keep track of both the current pulse and the trend of its changes.

THE OPERATING CONDITIONS

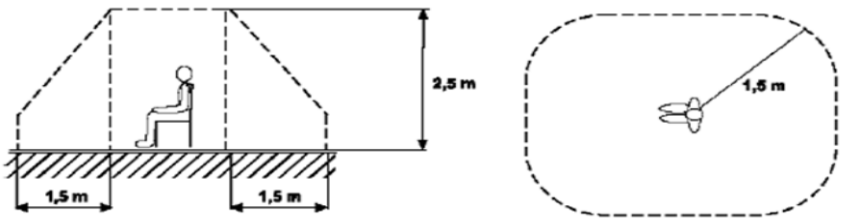
It is advisable to get the device worked at room temperature with moderate humidity. Mechanical shocks must be avoided. Caution requires ultrasonic probe, which can be destroyed on impact with a hard surface.

The output cable from the head is carried the weight of the decaying strain relief. Please do not break it at work or in transport or storage. The figure shows at the top of the inadmissible way bending the cable, at the bottom the course correct.

It is recommended to use only certified ultrasound gel – CE marked. Do not remove the remnants of ultrasound gel by scrub off. The probe can be cleaned with a cotton swab or soft cloth moistened with water or a mild disinfectant. You can use isopropanol 70% soaked pads. Excluded are all hot disinfection processes. Do not soak connectors. If you need to sterilize the probe gas or plasma sterilization is permitted. The housing and device clean with a wet cloth softly wipe screen. It is not, however, allowed ingress of any liquids inside the enclosure. The manufacturer recommends that you make the services. They should be carried out in the third, fifth, seventh, eighth and ninth of the year from the date of purchase. Life-time of the instrument the manufacturer specifies for 10 years. The first recommended service shall be done within 3 years (that take into account the minimum live time properly operated battery). In the case of long interruptions in use remember to recharge.

Documentation with PC

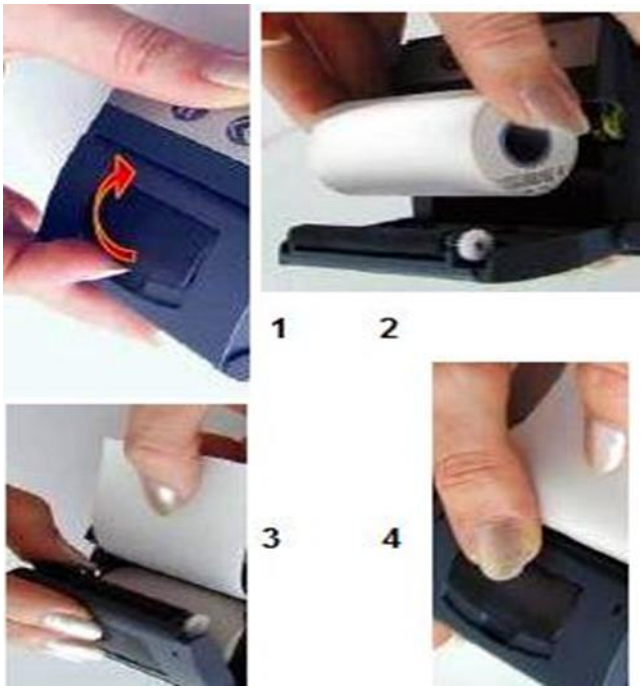
The optional PC output should be connected to PC with USB to miniUSB A/A cable. For installation and application follow instruction provided with software. As the PC is not a medical device it should be outside the patient environment when used with UD48V (as sample shown on the sketch):



Description of markings

Symbole zasilacza	**Opis / *Description***	**Symbole Pozostałe**	**Opis / *Description***
C US	Znaki w USA Kanada. *UL approval mark. Valid in the USA and Canada.*		Zapoznaj się z instrukcją *Read user instructions*
	Certyfikat od SIQ Approval mark of SIQ		WEEE dyrektywa *WEEE directive*
IP40	IP-Klasyfikacja *IP codes*		Częśc aplikacyjna B Aplication part type B
FWGB	Znak producenta *Trade mark of the manufacturer*		Uwaga na instrukcje - please observe instructions
ta xx / x	Klasa temperatur *Rated – ambient temperature / transformer class*		Złącze komputera Interface to PC
	Klasa izolacji II *Class II equipment*		Gniazdo zasilacza Power supply socket
V xxxx Q xxxx	Oznaczenie na Australiię *Approval mark of Australia*	CE	Deklaracja Zgodności 93/42/EWG *Declaration of Conformity acc.*

Operation of the printer - paper recorder



The recorder is built in the front side of the device. To proceed with the work, you must first place the roll of thermal paper. After pulling the lever located in the middle of the printer lift the lid and insert the roll so that the edge of the paper freely extends beyond the rubber roll. When you have the paper so that it does not raise the cover and Askew went to push in the middle part. Place the paper roll so that the active side of the paper tape on the outside in the outer part of the recorder from the top.

The printer prints the selected parameters from memory or current course: the date and time of the entry, in the form of presentations, index values, the scale and speed of the channel A and B and registered the curve currently visible on the screen.

To print a process on the level of the archive: Only the image from the screen is printed and the recorder will automatically stop. It's impossible to stop printing before the end. When paper is out a message will be displayed on the LCD while trying to record. You can only use paper for printers with thermal head, high resolution (unprinted), on a roll with an outside diameter of up to 32 mm. Thermal head in printer is a gentle, precise element and avoid touching it, soiling (e.g. ULTRASOUND gel) etc. Before the introduction of paper, make sure that the edge of the paper is equally truncated, as jagged could block and damage the recorder.

Note:

-If the paper when plotting moving and do not see anything on it, check that the thermal printer paper is applied and if it is positioned active side tothe printhead (up)

-When the device is running on battery (not connected to a mains) for the battery must be well charged (with low battery the printer does not print the record measurement)

Electromagnetic compatibility recommendations

Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
DOPPLER device are intended for use in the electromagnetic environment specified below. The customer or the user of DOPPLER device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	DOPPLER device use RF energy only for their internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The DOPPLER device are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
DOPPLER device are intended for use in the electromagnetic environment specified below. The customer or the user of DOPPLER device should assure that it is used in such environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be At least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains Power quality should be that of typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differentia mode ±2 kV common mode	±1 kV differentia mode ±2 kV common mode	Mains Power quality should be that of typical commercial or hospital environment.
Voltage dips, short interruption and voltage variations on Power supply input lines IEC 61000-4-11	< 5% Uт (>95% dip in Uт) for dla 0,5 cycle 40% Uт (60% dip in Uт) for 5 cycles 70% Uт (30% dip in Uт) for 25 cycles < 5% Uт (>95% dip in Uт) for 5 sec	< 5% Uт (>95% dip in Uт) for dla 0,5 cycle 40% Uт (60% dip in Uт) for 5 cycles 70% Uт (30% dip in Uт) for 25 cycles < 5% Uт (>95% dip in Uт) for 5 sec	Mains power quality should be that of typical commercial or hospital environment. If the user of DOPPLER device requires continued operation during power mains interruptions, it is recommended that DOPPLER device are powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic fields IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: Uт is the a.c. mains voltage priori to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
DOPPLER device are intended for use in the electromagnetic environment specified below. The customer or the user of DOPPLER device should assure that it is used in such environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the DOPPLER device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	d = 1.17 √P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz do 2,5 GHz	10 V/m	d = 0.35 √P 80MHz to 800MHz d = 0.7 √P 800MHz to 2,5GHz where P is the maximum output power rating of the transmitter in watts (W) manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each level frequency range. [d] Interferences may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency ranges applied.

NOTE 2 These guidelines May not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a The ISM (industrial, medical and scientific) bands between 150kHz and 80MHz are 6,765MHz to 6.795MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b The compliance level in the ISM frequency bands between 150kHz and 80MHz and in the frequency range between 80MHz and 2.5GHz intend to reduce the likelihood of mobile and portable communication equipment causing interference if they are brought inadvertently to the patient's environment. Therefore, an additional factor of 10/3 is used to calculate the advisable distance of separation for transmitters in these frequency ranges.

C The field intensities established by the fixed transmitters, such as base radio stations, telephones (cell phone/wireless) mobile land radio transmitters, amateur radio transmitters, AM and FM radio and TV transmission cannot be forecast theoretically with any accuracy. In order to evaluate the electromagnetic environment due to fixed RF transmitters, it is advisable to execute an electromagnetic inspection of the site. If the measure of the field intensity on the site where the DOPPLER device are used exceeds the level of RF compliance used above, DOPPLER device should be observed to check if the operation is normal. If abnormal performance is observed, additional procedures may be required, such as reorienting or repositioning DOPPLER series monitors.

D Above the range 150kHz thru 80MHz, the field intensity should be less than 10]V/m.

Recommended separation distances between portable and mobile RF communication equipment and DOPPLER device

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

Rated maximum output power of transmitter [W]	**Distance of separation according to the frequency of the transmitter [m]**		
	150 kHz to 80 MHz outside ISM bands $d = 1.17 \sqrt{P}$	**80 MHz thru 800 MHz** $d = 0.35 \sqrt{P}$	**800 MHz thru 2.5 GHz** $d = 0.7\sqrt{P}$ 800MHz to 2,5GHz
0,01	0.117	0,035	0.07
0,1	0.37	0.12	0,23
1	1.17	0.35	0.7
10	3.7	1.11	2,3
100	11,7	3.5	7

For transmitters with a nominal maximum output power not listed above, the advisable distance of separation d in meters (m) can be determined by using the equation applicable to the frequency of the transmitter, where P is the nominal maximum output power of the transmitter in watts (W) according to the manufacturer of the transmitter.

NOTE 1: At 80MHz and 800MHz, the distance of separation for the highest frequency range is applied.

NOTE 2: In the ISM (industrial, medical and scientific) frequency bands between 150kHz and 80MHz there are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3: An additional factor of 10/3 is used to calculate the advisable distance of separation for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80MHz to 2.5GHz to reduce the likelihood of interference that the mobile/portable communication equipment could cause if taken inadvertently to areas of patients.

NOTE 4: These directives may not be applicable in every situation. Electromagnetic transmission is affected by the absorption and reflection of structures, objects and people.

Climatic operation conditions

The device should be operated within the range of environment temperature from 10^{o}C to 45^{o}C by relative humidity not exceeding 85% and atmospheric pressure 70-106 kPa.

UD48V is not intended to operate in presence of anesthetic gases.

It is recommended that the device be operated at room temperature with moderate humidity. Mechanical shock is to be avoided, and special precautions are needed with the ultrasonic probe since it can get damaged when hit by a hard surface. The probe can be cleaned by means of a soft tissue, dampened with water or alcohol (70% isopropanol). The mild disinfection liquids only are recommended. When the probe requires sterilization only cold processes are allowed (gas, plasma). Do not soak connectors.

Repairs to the device

In case of damage or of any queries whatsoever, concerning the correct operation of the device, please contact service. Don't open the casing – there are no elements inside designed to be operated by user.

Transportation

temperature	-10 ¸ 50° C,
humidity	< 90 %,
preassure	500¸1060 hPa.

Short technical specification:

Ultrasonic frequency	8 MHz and/or 4MHz optionally 16MHz
Acoustic power (on the loudspeaker)	over 0,6 W
Ultrasound output	P_<1MPa, Iob<20mW/cm2, Ispta<100mW/cm2
Power supply - rechargeable battery	7,2 V, 3 Ah
Size	30 x 23 x 12 cm
Weight	2,2 kg
Recorder	thermal, tape width 58 mm, Roll length up to 20 m
Flow velocities	up to 240cm/s with accuracy 10% *

* The velocity calculation is based on 60 degree Doppler angle, the angle deviation has primary influence on the velocity values as a cosine function.

Completion:

- flow meter
- ultrasonic probe (as specification)
- battery charger
- operation instruction
- guarantee chart

 AC adapter Friwo FW7555_M09

The device is configured with:

- built-in thermal printer
  paper tape roll for recorder with thermal head
- connector for PC transmissions,
- 4MHz and 8 MHz probe, (16MHz option)

Transducers: CW4; CW8, option SPW16. Optional PPG probe.