User Manual

PulsePenLab

PulsePenLab is a device manufactured by DiaTecne s.r.l.

This manual is an integral part of the product and must be kept together with it.

Index

1. Description

The PulsePenLab is a non invasive device for the Pulse Wave Velocity assessment in small laboratory animals. It provides an enhanced sensitivity, a reduced plunger size and a higher sample rate than the standard devices. The PulsePenLab allows for longitudinal studies with repeated measurements during the life of the animals, avoiding their sacrifice, in opposition to the invasive method. Moreover the required time for examinations is quite short compared to the invasive method. Animals are sedated and put in place directly on a metal plate or interposing a heated layer for better comfort. The pressure probes are positioned on adjustable arms with micromanipulators. No Ecg is required (no electrodes must be connected to the animal's skin) because the PWV is derived directly by the transit time of the pulse waves captured by the two probes.

The device consists of the following parts:

- Tonometric Pressure Probes (2 x)
- Base Unit (1x) - battery powered
- Fiber Optic Adapter (1x) with optical fiber
- Mechanical Assembly
- USB Memory with Software
- Transport Bag and accessories

The package includes the printed copy of the User Manual and the Guarantee Certificate.

Below, speaking of "device", we refer to all the units that compose it unless otherwise indicated. Each unit, individually, does not provide any useful results.

The AA - Alkaline 1.5 V - IEC LR03 batteries are supplied together with the device solely for the purpose of allowing immediate use upon receipt of the package. These are readily available and very commonly used batteries. It is the user's responsibility to replace them when the remaining capacity is low, as indicated by the flashing light on the base unit of the PulsePenLab turning red.

The PulsePenLab must be connected to a computer, provided by the user, in order to view, record and analyze the signals. The connection to the computer is galvanically isolated as it is made through the optical fiber via the AF002 unit.

To calibrate the device, the systolic and diastolic pressure measurements taken with a user-supplied blood pressure monitor must be manually entered on the computer.

2. Intended Use

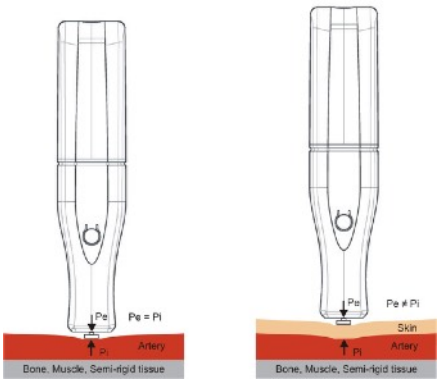
PulsePenLab is an active device, intended for recording the arterial pressure curve and evaluating the arterial stiffness, using the "Applanation Tonometry" method. The above device is not a sterile device.

3. Classification

The PulsePenLab device is intended for veterinary laboratory research purposes only

4. Principle of Operation

The operation of the device is based on the method of "applanation tonometry" which consists in exerting a slight pressure on a superficial artery from the outside, so that the artery flattens itself slightly against rigid or semi-rigid structures (bone , muscle, ...) below. In an ideal equilibrium situation (left figure) the internal arterial pressure (Pi) is equal to the external one (Pe). The pressure is detected by a sensor placed at the end of the Tonometric unit, which is also called "tonometric probe" or "tonometer" in the rest of the documentation. The pressure signal obtained from the sensor, appropriately amplified and digitized, is continuously acquired by the Tonometric unit and graphically presented to the user on the computer screen to which the device is connected.

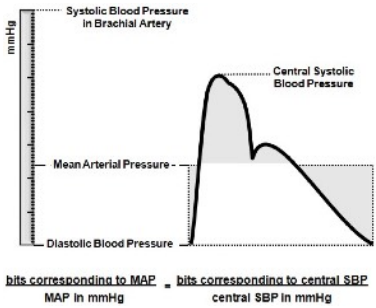


In the real situation, it is necessary to consider the presence of the skin and the superficial layers between the sensor and the artery under examination (indicated with Skin in the figure): in this case the internal arterial pressure (Pi) is different from the external one (Pe). In fact, to flatten the artery it is necessary to exert an extra pressure from the outside that deforms the skin and the intermediate layers and furthermore the pulsatory pressure inside the artery is transmitted outwards attenuated by the intermediate layers themselves.

The mechanical characteristics of the skin, such as elasticity, thickness, consistency, ..., vary from subject to subject, with age, etc. and it is for this reason that a transcutaneous arterial tonometer is not able to establish the exact values of the systolic and diastolic blood pressure while preserving an identical morphology of the pressure curve.

Consequently, it is necessary to carry out a calibration at each examination using a blood pressure monitor that must be provided by the user.

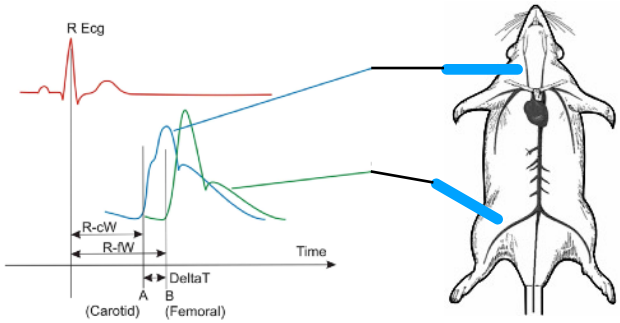
Calibration: the calibration of the acquired pressure values is based on the fact that the mean arterial pressure remains unchanged along the entire arterial tree, from the ascending aorta to the peripheral arteries, and also the difference between the values of the diastolic arterial pressure between the center and the periphery of the arterial system is insignificant. On the other hand, the value of the systolic pressure increases moving from the aorta towards the peripheral arteries due to the



reflected waves (phenomenon of amplification).
The mean arterial pressure of the sphygmic wave is defined, for each cardiac cycle, by the integral of the pressure curve, that is, the area it subtends. That said, the mean arterial pressure is estimated by:
MAP = DBP + x * (SBP-DBP) where x = 30 or 40%, and DBP e SBP are measured immediately before or after recording and entered manually by the user. Since the mean and diastolic pressure values are the same in the center and periphery, the difference between mean and diastolic pressure will also be constant. The software of the device, based on a simple equation, provides the value in mmHg of the arterial systolic pressure, knowing the value in mmHg of the difference between mean and diastolic pressure and the binary coding corresponding to the digitized signal.

5. Pulse Wave Velocity

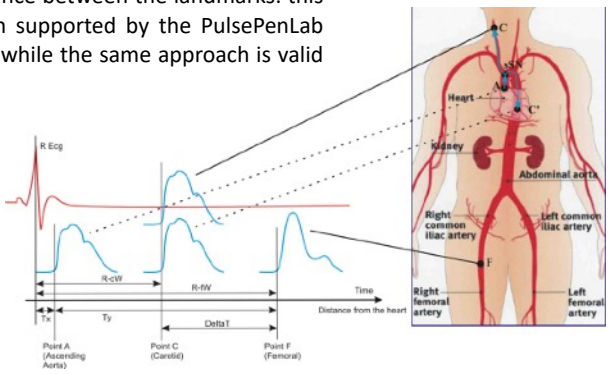
The pulse wave velocity (PWV) is defined as the ratio between the length of the arterial segment under examination (A-B in the figure) and the time taken by the pressure wave to travel through it: PWV = Distance / DeltaT (not to be confused with the speed of blood flow):



The PWV estimation is made by making a single recording with two tonometric probes positioned in the two reference points A and B to evaluate the "transit time" DeltaT (Carotid an Femoral arteries in the example).

6. Distance Measurement

A tape measure is used to measure the distance between the landmarks: this can be estimated mainly in two ways, both supported by the PulsePenLab Software. The figure shows the human case while the same approach is valid for animals:

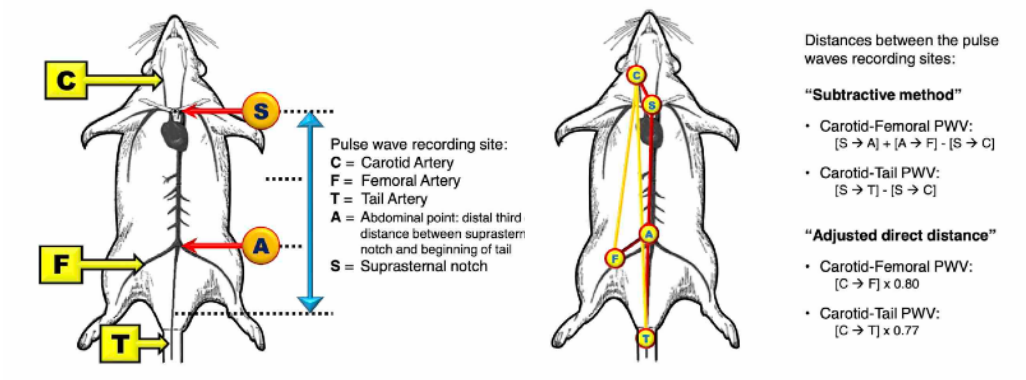


1) Direct Method:
The direct distance between the Carotid (C) and the Peripheral Artery (P_A), (F - Femoral in the example) is measured. The result is automatically multiplied by 0.8 by the software, according to the accredited guidelines.

2) Subtractive Method:
This method is based on the fact that the initial pressure wave, once it reaches the bifurcation at the

suprasternal notch (sSN in the figure), propagates both towards the Carotid and towards the Aorta. Assuming similar propagation characteristics in the two sections, when the rising pressure wave will have arrived in C (Carotid), the descending pressure wave will have arrived in C ', equidistant from sSN with respect to C. On the basis of these considerations, the distance actually traveled by the pressure wave corresponding to the DeltaT delay in the example in the figure, is equivalent to the segment C '- F and therefore distance = (sSN - F) - (C' - sSN) which can be approximated in distance = (sSN - F) - (C - sSN).

Whichever method is chosen, it is still necessary to enter the three distances (Carotid - P_A, sSN - P_A, Carotid - sSN) so that it is possible to calculate all parameters by the software.



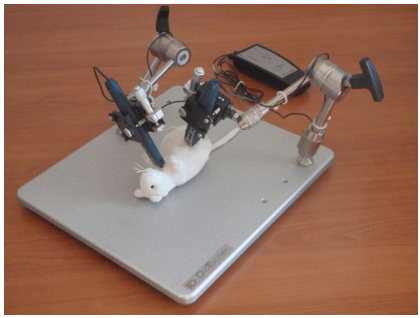
7. Arterial Stiffness

The theoretical model proposed by Bramwell and Hill and still accepted by the scientific community, defines distensibility as the percentage change in diameter for each increase in blood pressure of 1 mmHg.
The Arterial Stiffness is in turn inversely proportional to the distensibility and the pulse wave speed (PWV) is considered by the scientific community to be one of the main indicators of arterial stiffness.
In a young and healthy subjects, the arteries have great distensibility and therefore the pressure wave propagates slowly => low PWV values.
In an elderly subjects with calcification pathologies, for example, the arterial wall is rigid and therefore the pressure wave propagates quickly => high PWV values.
The structural characteristics of the arterial wall play a fundamental role in defining the transmission rate of the pulse wave.
Aorta and large elastic Arteries have a high content of elastin fibers having the task of making the blood flow continuous in the rest of the body: this is achieved by dilation during the systolic phase to store excess energy which is then returned during the diastolic phase, with the reduction of their lumen.
The PWV increment with the age is due to the change of composition of the arterial walls with a reduction of the ratio between elastin fibers and collagen fibers.
The Carotid-Femoral PWV increases with age and may be considered an index of biological age of the vascular system. Its increase is also caused by situations of arterial stiffness due to inflammation, calcification, ...

The peripheral arteries, on the other hand, are predominantly of the muscular type, adapting their lumen according to the sympathetic system and the relative PWV remains substantially unchanged.

8. Operational Setup

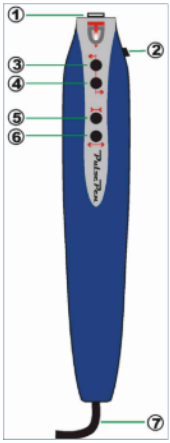
The figure shows an example of an operating configuration: the subject is sedated on the metal plate, usually with a heated layer between them for better comfort. The Tonometer probes are fixed to the micromanipulators and positioned according to the arteries to be examined. The base unit is connected to the PC via the optical fiber and the AF002 adapter.



9. Tonometric unit - TN004

1) Pressure sensor
2) Freeze button
3) Signal offset lowering button
4) Signal offset raising button
5) Signal attenuation button
6) Signal amplification button
7) Connecting cable for the Base Unit

Note: Buttons 2-6 aren't enabled for some Fw configurations



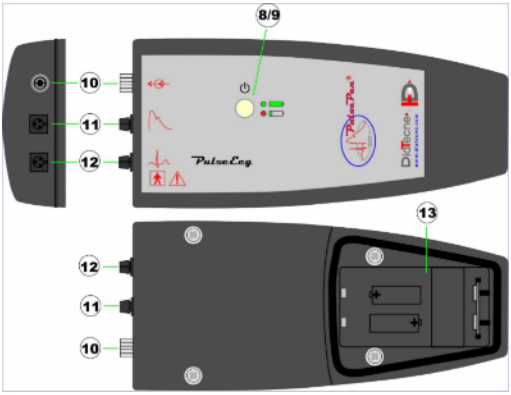
10. Base unit - EC004

8/9) On/Off button with battery life LED indicator

10) Fiber optic connector with ring nut for link with the Fiber Optic - USB Adapter

11/12) Connectors for Tonometric Probes

13) Battery compartment

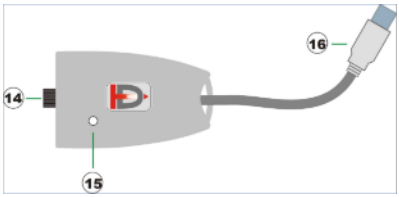


11. Fiber Optic - USB Adapter AF002

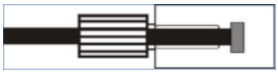
14) Fiber optic connector with ring nut for link with Base Unit

15) Data indicator LED

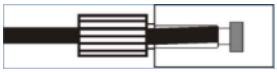
16) USB - P.C. Connector



Fiber correctly inserted



Fiber **NOT** correctly inserted



12. Software

PulsePenLab is the software for the capture, display, storage, and analysis of signals with the calculation of the parameters. It includes the subject database management. It's possible to make both short-term signal records (up to 10 ECG/ tonometric complexes) and long-term signal records (CTRL+S up tp 24 hours but in this case without signal analysis). This software allows for the generation of a subject report, the content of which must always be verified by a physician expert in the method. DiaTecne s.r.l. takes no responsibility for the final diagnosis.

To install the software included in the supplied USB pendrive, proceed by following the instructions given in the "readme.txt" file: the PulsePenLab software will be installed, with its icon on the desktop and the USB drivers for the AF002 receiver. Refer to "Usage Problems and Solutions" if you have difficulty.

13. Method of Use

Software Interface

fig. 1

1. New examination.
2. Access to the Subject Archive.
3. Setup and device programming.
4. “On line” instructions.
5. Data exchange between computer and AF002 (green under normal conditions).
6. USB drive connection (green if recognized correctly).
7. Not enabled
8. Not enabled
9. Not enabled
10. Data coming from AF002 waiting to be processed: a short bar signals a better situation to a long bar (it depends on the speed of the computer, other running programs,…).
11. Not enabled
12. Sensor1 corresponds to the red trace while Sensor2 corresponds to the blue trace.

Preparation for the exam

A. Insert the AF002 receiver into a USB port.
B. Start the PulsePenLab software.
C. Connect the Tonometer probes by inserting each cable connector into the corresponding 3-pin socket of the Base Unit (Sensor 1 in the center, Sensor 2 on the side).
D. Turn on the Base unit.
E. Insert the fiber optic cable into the specific connectors of the Base Unit on one side and the Fiber Optic - USB Adapter on the other.
F. The fiber must be pushed in all the way and fastened by gently screwing the outside ring nut.

Due to mechanical tolerance, and especially with new fibers, the optic fiber may appear to be completely inserted when it actually is not: see related image above.

In order to avoid damaging the connector, do not over tighten the ring nut. It’s enough that the fiber does not pull out during normal use of the equipment! Remember to unscrew the ring nut to loosen it before pulling out the fiber optic cable!

Functionality

New exam:

Select the icon  to start a new exam and choose a subject from those already in the archive or enter a new subject's data: at this point, the keys corresponding to the various arteries will be enabled.	

Carrying out the exam:

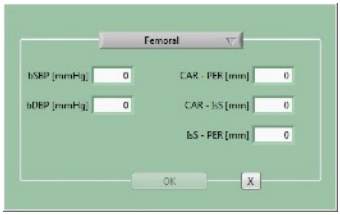
Turn on the device: when the button LED is green it means that the batteries are ok, while red indicates they are running down. In that case replace the batteries with new ones as soon as possible.

The LED on the AF002 adapter is on when the signal transmission on the Optic Fiber takes place.

Place the Tonometer probes on the region to be explored: the acquired signals will be displayed on the computer screen. Proceed according to the online software instructions.

Selecting the desired artery a new screen will open where the acquired signals will be displayed. The probe should be held perpendicular to the skin and not tilted. Once a series of complexes has been obtained, with a good quality, the operator can interrupt the acquisition by pressing the icon with the disk symbol or the Enter key, the last heart complexes recorded are automatically saved and analyzed. At this point, a window will appear for entering the systolic and diastolic pressure measured immediately before or after, with an external blood pressure monitor. The operator will also measure three distances, in millimeters: Carotid - Peripheral Artery, Carotid - Suprasternal notch and SupraSternal notch - Peripheral Artery.
In the estimation of PWV this allows to apply both methods of distance evaluation suggested by the international guidelines, i.e. both the "direct method" and the "subtractive method" - see the relevant paragraph.
At this point a new panel will show the parameters automatically calculated by the software.

Exam recording:

By pressing the icon with the disk symbol  or the Enter key, the last heart complexes acquired will be automatically saved and analyzed. At this point, a window will appear for entering the systolic and diastolic pressure measured with an external blood pressure monitor and for entering the distances between the landmarks.	

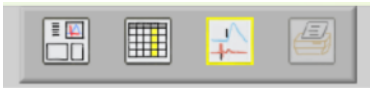
Determination of the arterial stiffness:

Immediately after saving the exam in progress or by recalling an exam from the subject database, the calculated parameters are automatically presented, including PWV (Pulse Wave Velocity) which represents the arterial stiffness index.	

Subject Database:

By selecting the "Subject Archive" icon  , all the subjects with their recorded exams are listed, from which it is possible to choose the one to display on the screen by clicking on it.	By selecting the exams in the related table, with the right mouse button, you can also choose: - Export: the exams are exported in DBD format useful for reimporting them into another PC with the PulsePenLab software. - Export ASCII: txt format with the exam examples listed in rows every millisecond. - Export CSV: the calculated mean values are listed in a spreadsheet (excel or similar) By selecting the subjects you have similar import/ export possibilities.

Showing Recorded Signals:

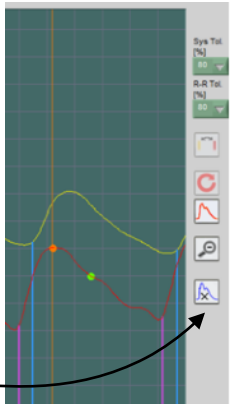
Selecting the "Signals" icon, the recorded waves are displayed on the screen.	

Selecting Tolerances:

When recording heartbeats in small laboratory animals it is common to get normal complexes interspersed with deformed complexes due to respiration. The PulsePenLab software allows you to automatically exclude defective complexes related to respiration from the parameter calculation. You can select both the tolerance in the amplitude of systolic values (Sys. Tol. [%]) and the tolerance in the R-R interval (R-R Tol. [%]). Higher tolerance values allow you to capture more heartbeats while lower values are more selective. You can change the tolerances and recalculate all parameters offline with this icon:	

Editing Markers:

- In case you want to manually exclude one or more beats from the calculation of the parameters, you can:
- Zoom In 
- Select the systolic red point of the wave
- Select this icon



Settings:

The settings are accessible by clicking on the icon

You can choose some parameters like the language, date format, …

Shutdown of device

- To turn off the instrument press and hold the on / off button of the Base unit until you hear a beep (after about 1 sec).
- The Base unit turns off automatically if no signal is captured by the Tonometer probes for a period of 5 min. to preserve the batteries: in fact, the stay in standby presupposes no acquisition of signals during this interval and therefore the inactivity of the same Sensors.

14. Commisioning

The PulsePenLab device does not require commissioning by personnel authorized and qualified by DiaTecne s.r.l.

15. Placement

The PulsePenLab must be kept in a closed environment - enclosed by walls while maintaining the environmental operating conditions (temperature, humidity, pressure) as reported in the technical characteristics in this manual. The degree of protection is IP20. The use of explosive gases, flammable substances or anesthetic gases is not allowed.

The device is intended for use in hospitals, medical clinics or research centers.

16. Maintenance and Cleaning

No particular maintenance operations or periodic calibration of the instrument are necessary for PulsePenLab.
Cleaning should be done before each use on a new subject and before storing the device in the case.

Base unit, Fiber optic adapter: use a soft, clean cloth slightly soaked in alcohol, avoiding infiltration inside.

Tonometer probes: use a soft, clean cloth slightly soaked in alcohol for the plastic shell, avoiding infiltration inside. Clean the sensor's plunger with the same cloth, acting gently and without pressing, avoiding infiltration inside.

Note: be very careful to keep the alcohol from penetrating into the Tonometer *probe because this could cause serious problems.*

17. Usage Problems and Solutions

Check and implement the following suggestions, from top to bottom, until the problem is solved.

The software installation does not complete:

- The installation of the software requires the operator to have the necessary permissions: in a hospital or research setting it is often necessary to contact the system administrator to proceed.

The Base unit does not turn on (no beeps):

- Check that the batteries are of the required type, inserted in the correct direction and are fresh.
- Keep the On / Off button pressed until the acoustic signal is heard (after about 1 sec).
- Remove and reinsert the batteries.

There are no signals to the computer:

- **fig. 1 - icon 6 red:** in this case the USB receiver - AF002 has not been recognized.
  - Close the software, remove and reinsert the AF002 fiber optical adapter and restart the software.
  - If the problem persists, it is recommended that you check with your system administrator that access to the computer's USB ports is not inhibited. Make sure that the presence of computer protection software such as Antivirus, Firewall, etc., does not prevent access to external USB devices.
  - With AF002 inserted, launch "DrvInst.exe" in the folder "Usb Driver" if the problem has not been solved with the previous suggestions.
- **fig.1 - icon 6 green and icon 5 red:** the AF002 unit is recognized correctly but the firmware in it installed is not compatible with the version of the software running on your computer.
  - Update firmware and / or software to the latest version. Contact DiaTecne s.r.l. in case of doubts or problems.

If it is not possible to solve the problems listed independently or if there are doubts about the operation of the device, please contact DiaTecne s.r.l. at the following email address: **info@pulsepen.com**. Assistance will be provided as soon as possible.

18. Mutual interference with other systems

The PulsePenLab device has been designed to be immune to electrical, electromagnetic, electrostatic and magnetic disturbances, normally present; similarly, the PulsePenLab produces a reduced quantity of disturbances towards the other devices. However, it cannot be excluded that, in particular situations, there may be operating anomalies also in the form of signal alteration: in this case it is necessary to remove all potential sources of disturbance when possible or move to a more appropriate location.

19. Technical Specifications

General

Capture	16 bit
Sampling Frequency	1000 S/sec
Electrical protection: Type EN 60601-1 Degree EN 60601-1	 Class II BF
Degree of protection against penetration of solids / liquids:	IP20
Electromagnetic Compatibility EN 60601-1-2 :	Group 1, Class B
Operating Ambient Temperature	from +5°C to +40°C
Transportation and Storage Temperature	from -25°C to +70°C
Relative Humidity	from 30% to 80% non-condensing
Atmospheric Pressure	from 860 to 1060 hPA
Accuracy of PWV estimation	better than ± 0.3 m/s (*)
Precision of PWV estimation	better than ± 1 m/s both intra-operator and inter-operator(*)

(*) Accuracy and Precision can be negatively affected by muscle tremors, breath, … and in general "noise" superimposed on the signal.

Optical fiber Adapter - AF002

PC connection	USB 1.0 / 2.0 - type A
Data transmission	2.2. mm Optical fiber / 3 m
LED	Operating mode signaling
Power supply	Self powered by the USB connector of the P.C.
Weight	30 g
Dimensions [mm]	57 (L) x 35 (W) x 18 (H)

Base Unit - EC004

Input connections	2 x PulsePenLab Pressure Probes
Output connections	Fiber optic cable
Button	On/Off with a bicolor LED that monitors the reserve of power
Acoustic Signals	Power on / off
Power supply	Two IEC LR06 -AA- Alkaline penlight batteries - Approximate autonomy: 40h
Vibrations	≤ 20 g @ 10 Hz - 2 KHz sinusoidal
Shock	≤ 150 g
Weight	87g without battery
Dimensions [mm]	144 (L) x 63 (W) x 31 (H)

Tonometric Pressure Probe - TN004

Resolution	0.00976 mmHg
Dynamic range	640 mmHg
Power / Output connections	Cable with connector for Base Unit
Sensor's plunger size	3.2 mm diameter (8.04 mm^2)
Max force to the sensor	1 Kg
Vibrations	≤ 2 g @ 10 Hz - 2 KHz sinusoidal
Shock	≤ 5 g
Weight	34g with cable
Dimensions [mm]	132 (L) x 23 (W) x 16 (H)

Batteries:

The technical characteristics that the batteries must meet in order to be used with the Base unit are fully specified with the abbreviation “AA - Alkaline 1.5 V - IEC LR06”.

- “AA” is the code that identifies the size of the batteries, 14.5 x 50.5 mm nominal.
- “Alkaline” identifies the internal chemical structure. It is a primary battery, i.e. non-rechargeable.
- “1.5 V” indicates the nominal no-load voltage of the fresh battery.
- "IEC LR06" is the IEC coding equivalent to "AA - Alkaline"

Computer:

The software that is part of the PulsePenLab must be installed on a computer provided by the user, whose characteristics are listed below, and equipped with at least one USB port where the AF002 unit can be inserted during operation.

The optical fiber connection between the AF002 unit and the other components of the PulsePenLab, make the computer galvanically isolated from the other parts of the instrument.

Specifications

Clock Frequency	≥ 2GHz
Ram	≥ 2 GB
Free Hard Disk	≥ 4.5 GB (SW + Database)
Graphic Resolution	≥ 1280 x 800, 24 bit color
Operating System	Windows® XP SP2/3, Vista, 7, 8, 10, 11 - 32/64 bit
Browser	HTML5 compatible (*)
USB ports	USB 1.0 / 2.0 - type A
Font	"Arial" installed for a correct representation of the text
Safety/EMC	Compliant to IEC 60950-1 or IEC 62368-1. The mains power supply must be of medical type, compliant with EN 60601-1, or alternatively an isolation transformer must be used. EMC: compliant to the CISPR 32 - EN 55032 standard.
Marking	CE or other valid in the Country of use

(*) required for Help/Tutorial view. Browser - version: Safari -12.1.1, Chrome - 75.0.3770.100, FireFox - 67.0.4, Opera - 60.0.3255.170 and later versions.

There are no particular constraints on the features that are not specified here such as single-core / multi-core CPU, shared / dedicated graphics card memory, type of GPU, minimum screen size, etc.

The computer can be powered by both the mains and its own internal battery, if present, always respecting safety standards and never using multiple sockets (power strips).

Install an antivirus software.

Check with the system administrator that access to the computer's USB ports is not inhibited and make sure that the presence of computer protection software such as Antivirus, Firewall, etc., does not prevent access to external USB devices.

20. General Precautions and Warnings

It is very important to read the following warnings carefully before using the device. Improper use can have very serious consequences.

- Remove the batteries in case of prolonged non-use.
- Use only 1.5V batteries of the indicated type. Batteries of a type other than that prescribed can damage the device.
- Insert batteries as shown and check their condition before each use (dead or damaged batteries can cause acid leakage).
- Pay close attention so that alcohol, other liquids and dust do not penetrate inside the Tonometric sensor or other units because this could cause serious problems, irreparably damaging the internal parts.
- Do not use the device in the operating room and in any case in the presence of flammable gases / substances.
- Do not use the device for intracardiac applications or in direct contact with internal parts of the body.
- Use the device only on intact skin surfaces.
- Do not sterilize the device either in an autoclave or with liquid substances.
- Do not subject the Tonometric sensors to mechanical shocks such as bumps or falls.
- Keep the units at a distance from the computer no less than 1.5 meters.
- Do not immerse any part of the device in water or other substances or subject it to splashes. Never use Gel on the Tonometric sensor.
- Do not carry out maintenance on the device that involves opening it; in case of device malfunction contact DiaTecne s.r.l.
- Do not use the device in case of breakage of any part, do not proceed with repair attempts but contact DiaTecne s.r.l. for repair / replacement.
- Do not make any modifications of any kind to the device and do not use any accessories other than those supplied.
- Keep the Tonometric probe and other parts away from power outlets and surfaces where potentially dangerous voltages are present.
- Use a battery-powered computer (laptop) or alternatively a mains-powered computer that complies with current medical standards as reported in the related specifications.
- Use the device away from electromagnetic interference sources such as for example “cordless” telephones operating at radio frequency, cellular phones, Bluetooth and WiFi devices or other devices that emit high frequency electromagnetic waves.
- Do not turn on or use the device if the battery compartment is not properly closed.
- During the recording of the carotid pressure curve, compression of the carotid bulbs could accidentally induce a reduction in heart rate. It is strongly recommended that the examination be interrupted when bradycardia occurs. It should also be remembered that simultaneous compression of the carotid bulbs must be avoided, as it can cause syncope due to arterial hypotension or severe bradyarrhythmias.
- Periodically make backup copies of the subject archive. DiaTecne s.r.l. assumes no responsibility for the loss of data in the archive.
- Reduce the likelihood of radio interference occurring. Make sure that the WiFi and Bluetooth of the computer and mobile phones are turned off while using the PulsePenLab or alternatively activate the 'airplane mode' on these devices.

- In the event of adverse events and / or serious accidents involving the device, the user is required to notify the manufacturer and the competent authorities of his Country.
- Use the device only for the purposes specified in this manual.
- DiaTecne s.r.l. cannot be held responsible for damage caused to people, animals or things in the event that the user does not scrupulously follow the instructions in this manual.

The Tonometric probe cable is very thin and flexible in order to be easy to handle.
One must avoid pulling, and bending it at a right angle so as not to damage it.
Do not pull, twist or bend the cable near the probe !

Optical Fiber can be damaged if trodden upon, or bent at an angle!

Do not pull or bend the cable near the connector !

Do not twist the cable near the connector !

21. Useful Life

The useful life of the device is limited by the obsolescence of the components and by the use, respecting the indications given in this Manual.
The declared useful life is 5 years from the manufacturing date.
At the end of its useful life, a check may be carried out by DiaTecne s.r.l., for the extension of the same, otherwise the device must be disposed off as indicated in this Manual.
The manufacturer DiaTecne s.r.l. cannot be held responsible in any case for the use of the device beyond the declared useful life.
The guarantee conditions relating to the device are indicated in this Manual and in the Guarantee Certificate.
The shelf life (maximum period for which the device can be stored without being used) is declared as a precaution equal to 10 years from the date of manufacture.

22. Disposal

DiaTecne s.r.l. is sensitive to environmental issues related to the production of waste.
The user who will have to dispose this device once it has reached the end of life, must contact DiaTecne s.r.l. and follow the instructions he will receive.
Adequate separate collection for subsequent recycling, treatment and environmentally friendly disposal, helps to avoid possible negative effects on the environment and human health and favors the reuse and / or recycling of the materials of which the device is made.

Note that the illegal disposal of the product involves the application of the penalties provided for by the legislation in force in the Country in which this occurs.

Exhausted batteries must be disposed off by placing them in the appropriate containers, as they are waste with high polluting power.

23. Symbols and Abbreviations

It's mandatory to read the User Manual before using the device

Manufacturer's Data

CE conformity Mark
The code of the Notified Body is next to the symbol

Model

Identification symbol of the device configuration - Product Code

Serial number identification symbol

Insulation Class II

The product at the end of its useful life must be disposed off as electronic waste, separately from other waste

Battery symbol. Type "AAA - Alkaline 1.5V - IEC LR03"

Pay Attention

24. Labels

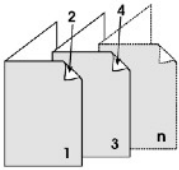
The label with the identification data is located on the Back of the metal plate of the mechanical assembly.

Each part of the device, in order to be identified, has its own label showing its code (REF) together with the serial number (SN).

25. Various

Document printing:
Additional copies of this document can be printed as follows:

- Open the “pdf” file of this manual with Adobe Reader or similar
- Select the options "booklet", “both sides", "left binding", "A4 paper size", "portrait orientation”
- Print both sides, fold and bind as shown:



With a view to continuous product improvement, DiaTecne s.r.l. reserves the right to make any changes it deems necessary, both to this manual and to the PulsePenLab device, without prior notice, notifying the competent authorities only.

Notes:

Notes: