



User Manual *PulsePen*



PulsePen 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

	page
1. Description	3
2. Intended Use	4
3. Classification	4
4. Patients and Users	5
5. Principle of Operation	5
6. Pulse Wave Velocity	6
7. Distance Measurement	7
8. Arterial Stiffness	8
9. Clinical Benefit	9
10. Operational Setup	10
11. Signal Receiver unit - wRs1	10
12. ECG unit - wEc1	10
13. Tonometric unit - wTn1	11
14. Ecg Cable Set: CV010	11
15. Software	11
16. Method of Use	12
17. Commisioning	17
18. Placement	17
19. Maintenance and Cleaning	17
20. Usage Problems and Solutions	17
21. Mutual interference with other systems	18
22. Technical Specifications	19
23. General Precautions and Warnings	23
24. Recorded values of Electromagnetic Compatibility	25
25. Useful Life	29
26. Disposal	29
27. Symbols and Abbreviations	30
28. Labels	31
29. Various	31

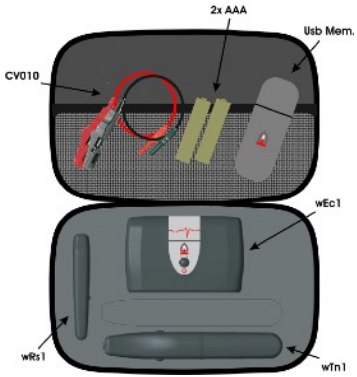
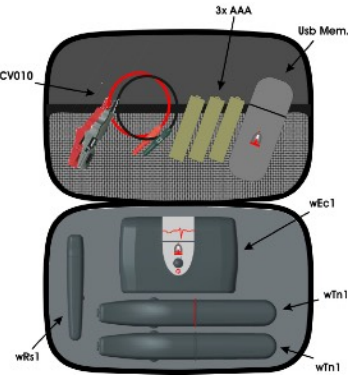
1. Description

The Medical Device (MD) object of this technical documentation is the "PulsePen", in the two available configurations as defined below. PulsePen is an active medical device, for diagnostic purposes, intended for recording the arterial pressure curve and evaluating the stiffness of the arteries, using the non-invasive method of "applanation tonometry".

The primary functions are the capture, display and storage of the arterial pressure signal in order to subsequently proceed with the calculation of the related parameters, including the pulse wave velocity (PWV), a parameter related to the stiffness of the arteries.

With this method, the sensor, which is part of the tonometric unit, also called the "tonometric sensor", is placed on an intact skin surface in correspondence with the arterial pulsation, exerting a modest pressure: the artery is consequently slightly compressed (applanation tonometry) and there is a balance between the circumferential forces inside the vessel. In this way the sensor records the pressure inside the compressed artery.

The medical device is available in two different configurations - REF: WPP001-ET and REF: WPP001-ETT, as shown below:


WPP001-ET	WPP001-ETT
	
1 Tonometric Unit: wTn1	2 Tonometric Units: wTn1
1 ECG Unit: wEc1	1 ECG Unit: wEc1
1 Signal Receiver Unit: wRs1	1 Signal Receiver Unit: wRs1
1 Ecg Cable Set: CV010	1 Ecg Cable Set: CV010
USB Memory with the WPulsePen Software	USB Memory with the WPulsePen Software
2 Batteries: AAA - Alkaline 1.5 V - IEC LR03	3 Batteries: AAA - Alkaline 1.5 V - IEC LR03
1 Case	1 Case


The MD consists of the following parts:


- PulsePen tonometric unit, from which the entire device takes its name, REF: wTn1, intended for the acquisition of the pressure signal with the non-invasive method of "applanation tonometry" and transmission via radio to wRs1. The number of such units included in the package varies from one, in the case of the configuration WPP001-ET, to two in the case of the configuration WPP001-ETT.
- ECG unit, REF: wEc1, intended for the acquisition of an electrocardiographic lead and transmission via radio to wRs1.
- Signal Receiver Unit, REF: wRs1, to be inserted in a computer USB port, intended for synchronization and reception of signals coming from wTn1 and wEc1.
- ECG cable set with "crocodile" terminals, REF: CV010.
- USB Memory with Software, REF: WPulsePen.


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 AAA - Alkaline 1.5 V - IEC LR03 batteries are supplied together with the MD 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 residual capacity reported by the PulsePen software is less than 10%.*

 *The PulsePen 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 via radio through the wRs1 unit.*

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

 *User-supplied disposable ECG electrodes must be used for ECG acquisition. The electrocardiogram is acquired exclusively to define the R wave to be used as a time reference for calculating the "transit time" of the pressure wave and not for making electrocardiographic diagnoses on the patient.*

2. Intended Use

PulsePen is an active medical device, for diagnostic purposes, 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

Class IIa medical device according to the Regulation (EU) 2017/745.

4. Patients and Users

The use of the device is indicated in all age groups. Subjects at risk for premature vascular aging, young people with isolated systolic hypertension and adults at cardiovascular risk.

Patient selection criteria:

Subjects of all ages at risk for premature vascular aging.

Young subjects with isolated systolic hypertension.

Cardiovascular risk subjects in which subclinical vascular damage is hypothesized.

Pregnancy and breastfeeding are not a contraindication to the use of the device.

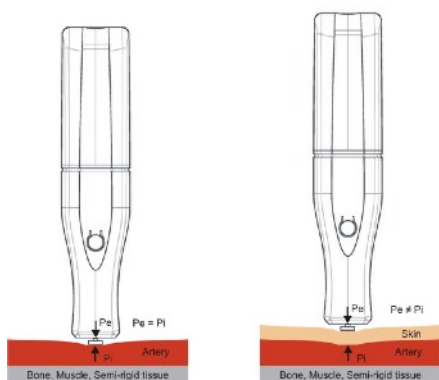
The neonatal age does not constitute a contraindication to the use of the device.

The user of the medical device is exclusively a professional user to be identified in personnel with a degree in medicine and surgery / master's degree in nursing sciences or equivalent qualifications in various countries, who are familiar with the "applanation tonometry" method. It is intended for use in hospitals, medical clinics or research centers.

It is not considered necessary to provide specific training for users, as the User Manual contains all the instructions for use.

5. Principle of Operation

The operation of the medical 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 (P_i) is equal to the external one (P_e). The pressure is detected by a sensor placed at the end of the wTn1 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 wTn1 Tonometric unit and graphically presented to the user on the computer screen to which the medical 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 (P_i) is different from the external one (P_e). 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.

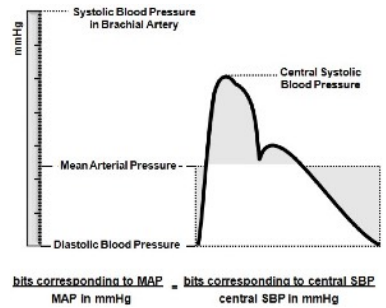
The mechanical characteristics of the skin, such as elasticity, thickness, consistency, ..., vary from patient to patient, with age, etc. and it is for this reason that a transcutaneous arterial tonometer is not able to establish

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 traditional

sphygmomanometer that must be provided by the user. This sphygmomanometer must be a certified medical device according to Directive 93/42/EEC or to the MDR Regulation.

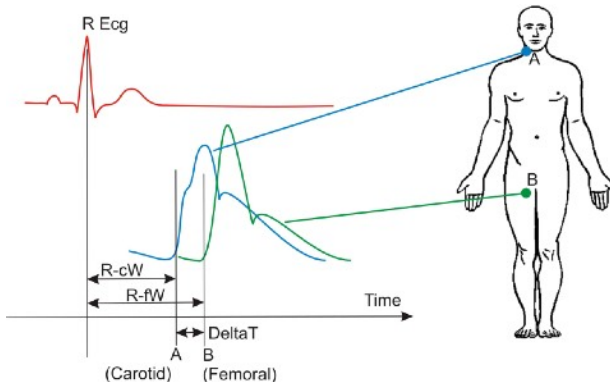
Calibration: the calibration of the acquired pressure values is based on the fact that the mean arterial pressure remains unchanged along the entire arterial tree, from the ascending aorta to the peripheral arteries, and also the difference between the values of the diastolic arterial pressure between the center and the periphery of the arterial system is insignificant (generally between 0.2 and 0.6 mmHg in the brachial artery relative to the ascending aorta). 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 calculated from the brachial systolic and diastolic blood pressure values measured with a traditional sphygmomanometer, immediately before or after recording with transcutaneous tonometry 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 medical 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.

6. 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: $PWV = \text{Distance} / \Delta T$ (not to be confused with the speed of blood flow). There are two ways to determine PWV:



1) By making two sequential recordings in the carotid artery and in the selected peripheral artery using the R wave of the ECG as a time reference. It is therefore obtained the delay of the pressure wave recorded in the carotid artery with respect to the R wave of the ECG (R-cW) and the delay of the peripheral pressure wave (the example shows a femoral artery) with respect to

the R wave of the 'ECG (R-fW). The difference between R-fW and R-cW represents the DeltaT which is the "transit time" of the pressure wave in the selected segment. This type of PWV determination can be obtained with both WPP001-ET and WPP001-ETT because both configurations have the wEc1 ECG

unit and at least one tonometric probe wTn1.

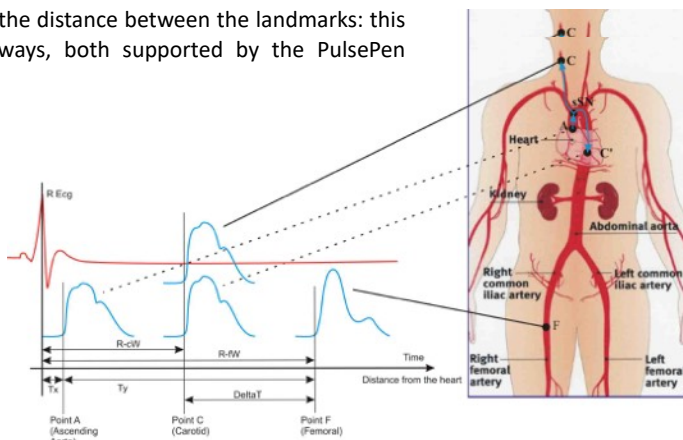
2) By making a single recording with two tonometric probes positioned in the two reference points A and B to evaluate the "transit time" DeltaT. This type of PWV determination can only be obtained with WPP001-ETT because it is the only one to have two tonometric probes. This mode is also useful in the case of a pathological ECG signal without a clearly identifiable R wave that can be used as a precise time reference. Other similar situations are the presence of pacemakers, atrial fibrillation, branch block, ..

7. 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 PulsePen Software:


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.

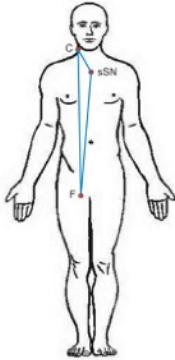


2) Subtractive Method:

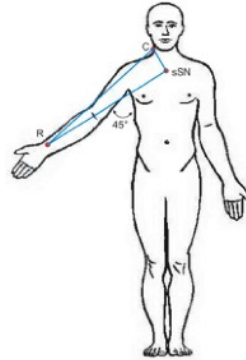
This method is based on the fact that the initial pressure wave, once it reaches the bifurcation at the suprasternal notch (sSN in the figure), propagates both towards the Carotid and towards the Aorta. Assuming similar propagation characteristics in the two sections, when the rising pressure wave will 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.*

Measurement of distances for the Femoral, Tibial, Dorsalis Pedis Artery: A tape measure is used to measure the distances between the Carotid Artery and the Peripheral Artery (Femoral in the example), between the Carotid Artery and the suprasternal notch and finally between the suprasternal notch and the Peripheral Artery.



Measurement of distances for the Brachial, Radial Artery: with the arm at 45 degrees as in the figure, a tape measure is used to measure the distances between the Carotid and the Peripheral Artery (Radial in the example), between the Carotid and suprasternal notch and finally between the suprasternal notch and Peripheral Artery.



8. 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 person, the arteries have great distensibility and therefore the pressure wave propagates slowly => low PWV values.

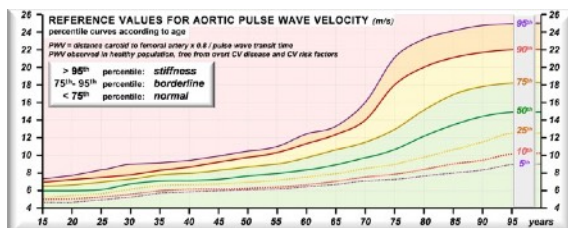
In an elderly person or subjects with calcification pathologies, for example, the arterial wall is rigid and therefore the pressure wave propagates quickly => high PWV values.

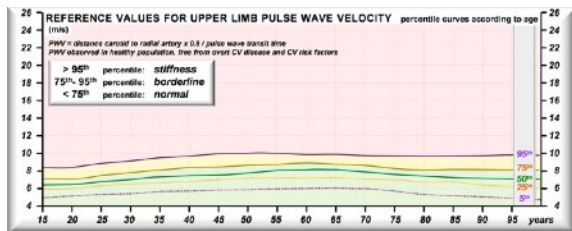
The structural characteristics of the arterial wall play a fundamental role in defining the transmission rate of the pulse wave.

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 image was derived from a healthy adult population and refers to the Carotid-Femoral segment with

PWV percentile curves in meters / second referred to the age: note how PWV increases with age. This is due to the change of composition of the arterial walls with a reduction of the ratio between elastin fibers and collagen fibers.





Peripheral arteries, on the other side, are mainly of muscular type, adapting their lumen according to the sympathetic system.

The image was derived from a healthy adult population and refers to the Carotid-Radial segment with PWV percentile curves in meters / second referred to the age: note how PWV remains almost constant with age.

In summary, we can say that:

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, ...

For this reason, it's considered the gold standard for assessing Arterial stiffness. On the other side, the Carotid-Radial or the Femoral-Tibial PWV does not significantly change with age and does not provide information on the biological age of the vascular system. The PWV in this case is mainly related to the activity of the sympathetic system.

9. Clinical Benefit

Improvement of the primary cardiovascular prevention. The diagnosis of a condition of arteriosclerosis, even clinically silent, configures a situation of subclinical organ damage, suggesting to the clinician a more in-depth evaluation of the patient, and possibly inducing changes in the treatment and advice relating to the patient's lifestyle.

Arterial Stiffness is considered an independent cardiovascular risk factor.

Clinical Condition to Diagnose, Treat / Monitor:

In addition to the diagnosis of arteriosclerosis and atherosclerosis, the examination allows the diagnosis of isolated holosystolic hypertension in young people and to highlight a condition related to a state of early vascular aging. The latter condition requires periodic monitoring of the parameters relating to the condition of vascular stiffness, in order to verify the response to therapy.

Contraindications

There are no contraindications to using the device.

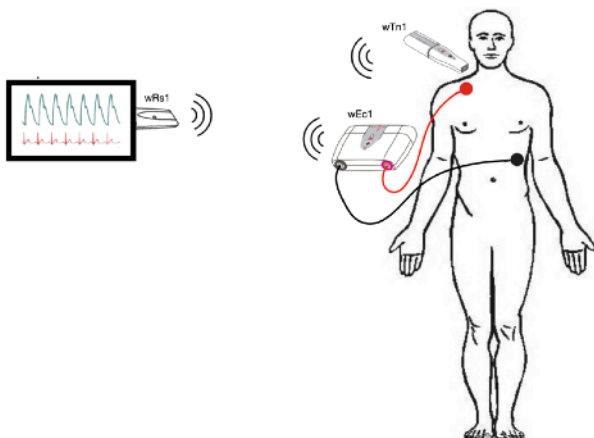
Potential clinical risks

Based on the reports in the literature, also referable to similar devices on the market, no dangerous situations related to the correct use of the device are detected.

A dangerous condition can be assumed if an attempt is made to perform with the WPP001-ETT the simultaneous recording of the pressure curves in the two carotids, with simultaneous compression of the carotid bulbs. The execution of this maneuver configures a known and evident guilty attitude of unskillfulness on the part of the professional user. There is no indication for the simultaneous recording of pressure curves in the carotid artery and, even if it is not the correct use of the instrument, this potential risk condition has been clearly indicated in this manual.

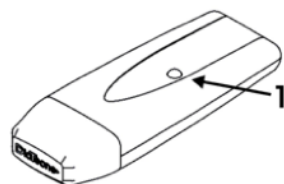
10. Operational Setup

The figure shows an example of an operating setup: the wRs1 unit is inserted into a USB socket on the computer where the PulsePen software is running and receives data wirelessly from wEc1 and wTn1.



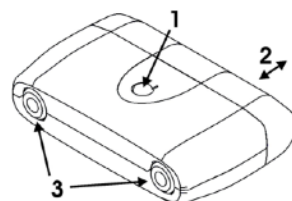
11. Signal Receiver unit - wRs1

1. Operating mode signaling LED. This LED blinks green when the PulsePen software is not running or if the USB driver is not properly installed. The LED is solid green during normal operations while it is red during reprogramming / updating.



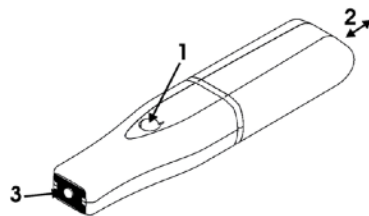
12. ECG unit - wEc1

1. On / Off button: keep pressed for about 1 sec.
2. Cap for battery replacement: pull away from the unit's body. Remove the old battery. Insert the new battery without ever forcing and respecting the polarity indicated by the appropriate label. Put the cap back in its seat by pushing it until clicks.
3. Sockets for the patient ECG cable CV010.



13. Tonometric unit - wTn1

1. On / Off button: keep pressed for about 1 sec.
2. Cap for battery replacement: pull away from the tonometer's body. Remove the old battery pushing it from the side opposite the opening. Insert the new battery without ever forcing and respecting the polarity indicated by the appropriate label. Put the cap back in its seat by pushing it until clicks.
3. Active part of the tonometric sensor.



14. Ecg Cable Set: CV010

Red and black cables.

1. Crocodile for ECG electrodes
2. wEc1 side connector



15. Software

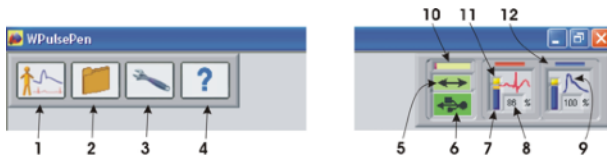
WPulsePen is the software for the capture, display, storage, and analysis of signals with the calculation of the parameters. It includes the patient database management. It's possible to make both short-term signal records (up to 10 ECG/ tonometric complexes) and long-term signal records (up to 24 hours but in this case without signal analysis). This software allows for the generation of a patient 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 drive, proceed by following the instructions given in the "readme.txt" file: the WPulsePen software will be installed, with its icon on the desktop and the USB drivers for the wRs1 receiver. Refer to "Usage Problems and Solutions" if you have difficulty.

16. Method of Use

Software Interface

fig. 1



1. New examination.
2. Access to the Patient Archive.
3. Setup and device programming.
4. "On line" instructions (Help / Quick Guide / Tutorial / Manual).
5. Data exchange between computer and wRs1 (green under normal conditions).
6. USB drive wRs1 connection (green if recognized correctly).
7. Graphic indication of the residual battery capacity of wEc1 and wTn1.
8. Remaining battery capacity of wEc1 and wTn1: replace the battery if less than 10%.
9. Icon representing the ECG (QRS) or Tonometric (pressure wave) signal depending on the type of active sensor.
10. Data coming from wRs1 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. The upper part of the battery symbol turns yellow in standby, i.e. when the "Freeze" is active or in situations other than that of "real time" acquisition and display of signals.
12. Sensor1 corresponds to the red trace (ECG or Tonometer) while Sensor2 corresponds to the blue trace (Tonometer only).

Preparation for the exam

- B. Start the WPulsePen software.
 - C. Insert the wRs1 receiver into a USB port and wait for the device to be recognized (fig. 1 - icons 5 and 6 green).
 - D. Extract the cap of the wEc1 and wTn1 units, insert the batteries in the appropriate compartment, strictly respecting the orientation indicated (see Warnings) and put the cap back in its seat.
 - E. Let the patient lie down on the medical bed.
- If you intend to carry out the examination with two tonometers at the same time, go directly to the next point "I".
- F. Using "fresh" pre-gelled disposable Ag / AgCl ECG electrodes for crocodile clips, place them in the following way:
 - Red: right subclavian region
 - Black: left subcostal region

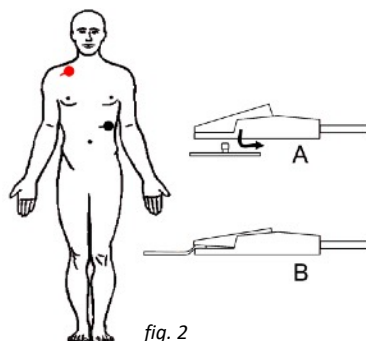


fig. 2

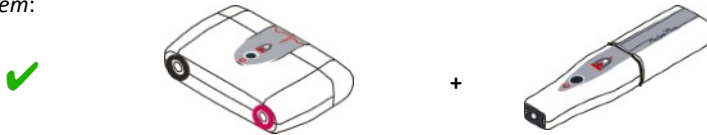
The suggested position can be changed at the operator's discretion in the presence of ECG signals that are too small, inverted or altered, for example due to pathologies. Direct contact of the electrodes with synthetic clothing which could cause disturbance must be avoided, in which case it is advisable to interpose a sheet of paper.

- G. Connect the crocodiles of the patient cable to the respective electrodes according to their type (type A or type B, see fig. 2)
- H. Insert the connectors of the opposite end of the ECG cables into the corresponding sockets of wEc1.
- I. Turn on the units you intend to use (wEc1 and wTn1 or two wTn1) holding down the on / off button until you hear a beep (after about 1 sec). wEc1 produces a single “beep” as well as wTn1 programmed as Sensor1 (red trace) while wTn1 programmed as Sensor2 (blue trace) produces two “beeps”.

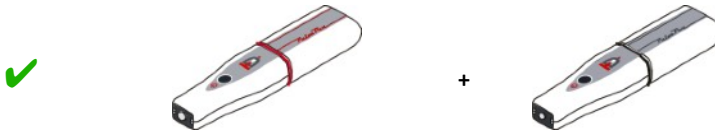
Permitted Sensor Combinations

The correct use of modules wEc1 and wTn1 is based on the assumption that one of the two is set as Sensor1 and the other as Sensor2: wEc1 is always set as Sensor1 and cannot be changed while wTn1 can be set in two ways: refer to the Help online of the software for operating instructions.

wEc1 - Sensor1 (1 beep when switched on) + wTn1 set as Sensor2 (2 beeps when switched on). *These are the factory settings for the WPP001-ET system and for the wTn1 unit with the black ring of the WPP001-ETT system:*

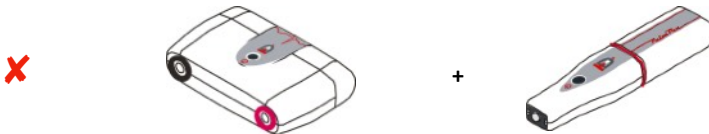


wTn1 set as Sensor1 (1 beep when switched on) + wTn1 set as Sensor2 (2 beeps when switched on). *These are the factory settings respectively for the wTn1 unit with red and black ring of the WPP001-ETT system:*

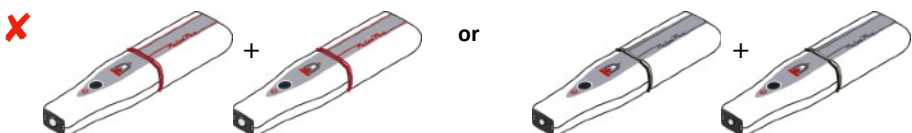


Wrong Sensor combinations

wEc1 - Sensor1 (1 beep when switched on) + wTn1 set as Sensor1 (1 beep when switched on):




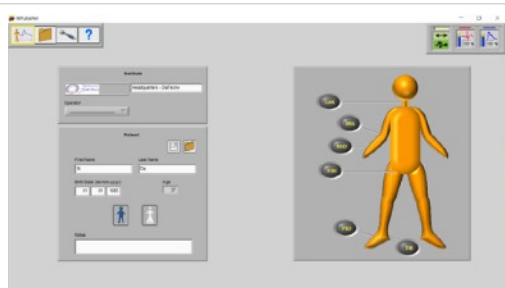
Both wTn1 modules set as Sensor1 (1 beep when switched on) or as Sensor2 (2 beeps when switched on):



Functionality

New exam:

Select the icon  to start a new exam and choose a patient from those already in the archive or enter a new patient's data, such as name, surname, date of birth, sex: at this point, the keys corresponding to the various arteries will be enabled.



Carrying out the exam:

Selecting the desired artery a new screen will open where the acquired signals will be displayed once the wTn1 probe(s) has(have) been positioned on the region to be explored. An automatic signal "Freeze" function stops the acquisition when no activity is detected on the wTn1-Sensor2 tonometer (blue trace). The operator must firmly rest his elbow and hold the wTn1 probe as shown in fig. 3 with the fingertips in contact with the patient's skin, thus minimizing tremors. The probe should be held perpendicular to the skin and not tilted. It is advisable to consult the Quick Guide contained in the Help-Tutorial. Once a series of overlapping complexes has been obtained, indicated by the green color of the traffic light at the top of the screen (see the software Help), the operator can interrupt the acquisition by lifting the wTn1-Sensor2 tonometer. By pressing the icon with the disk symbol or the Enter key, the last heart complexes recorded, up to a maximum of ten, 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 sphygmomanometer. In the case of a peripheral Artery, the operator will also have to use a meter to obtain 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.

Refer to the online Help for all the additional features available.

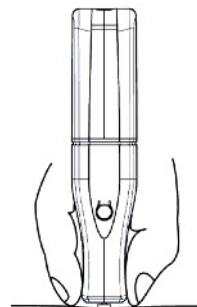
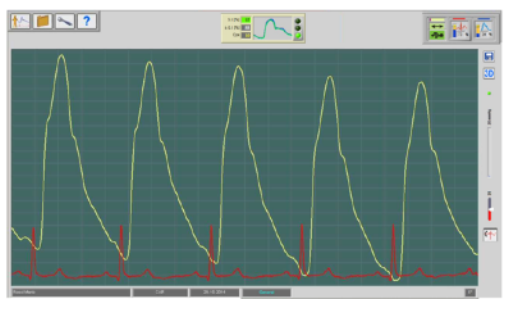



fig. 3

Place the wTn1 probe (or two probes in the case of the WPP001-ETT model) on the region to be explored: the acquired signals will be displayed on the computer screen.



Once a series of overlapping complexes have been obtained, indicated by the green light of the traffic light in the upper central part of the screen, the operator can interrupt the acquisition by lifting Sensor 2.

Exam recording:

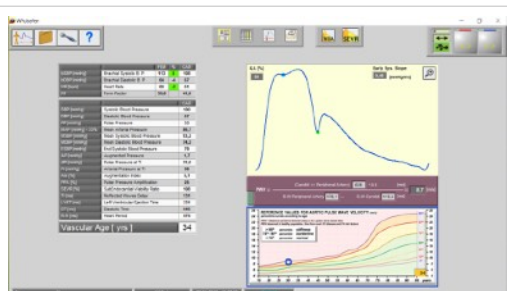
By pressing the icon with the disk symbol  or the Enter key, the last 10 heart complexes acquired will be automatically saved and analyzed. At this point, a window will appear for entering the systolic and diastolic pressure measured with a sphygmomanometer and for entering the distances between the landmarks.

Viewing stored exams:


Access the patient database and choose the patient and exam to view. Refer to the "Patient Database" point.

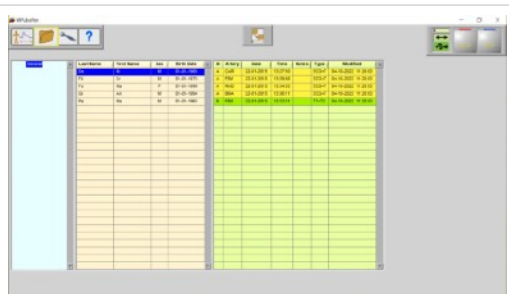
Determination of the arterial stiffness:

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



Patient Database:

Selecting the "Patient Archive" icon  lists all patients with their registered exams, from which you can choose the one to be displayed on the screen.




Settings:

The settings are accessible by clicking on the icon



You can choose the language and date format, program the sensors (radio channel, sensor 1/2, firmware update), set the tolerance levels, choose the method of calculating the mean arterial pressure.



The icon  allows you to access the online Help.

Shutdown of device

- To turn off the wEc1 and wTn1 Sensors, press and hold the on / off button until you hear a beep (after about 1 sec).
- wEc1 and wTn1 turn off automatically when the program is exited or if there is no connection with the wRs1 unit for more than 30 seconds, for example if the WPulsePen software is not running or the distance between the units is excessive. The wEc1 e wTn1 Sensors also turn off automatically if they remain in standby for more than 10 minutes to preserve the battery: in fact, the stay in standby presupposes no acquisition of signals during this interval and therefore the inactivity of the same Sensors.



The wEc1 and wTn1 units do not transmit radio frequency until the connection with wRs1 is established.

17. Commissioning

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

18. Placement

The PulsePen 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.

19. Maintenance and Cleaning

No particular maintenance operations or periodic calibration of the instrument are necessary for PulsePen.

Cleaning should be done before each use on a new patient and before storing the MD in the case.

wRs1, wEc1: use a soft, clean cloth slightly soaked in alcohol, avoiding infiltration inside.

CV010: use a soft, clean cloth lightly soaked in alcohol for the cables, the "crocodiles" and the connectors at the ends.

wTn1: use a soft, clean cloth slightly soaked in alcohol for the plastic shell, avoiding infiltration inside. Clean the metal disc of the sensor with the same cloth, acting gently and without pressing, avoiding infiltration inside.

20. 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 wEc1 / wTn1 unit does not turn on (no beeps):

- Check that the battery is the required type, inserted with the correct orientation, and that it is fresh.
- Keep the On / Off button pressed until the acoustic signal is heard (after about 1 sec).
- Remove and reinsert the battery.

There are no signals to the computer:

- **fig. 1 - icon 6 red:** in this case the USB receiver - wRs1 has not been recognized.
 - Close the software, remove and reinsert the wRs1 signal receiver 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 wRs1 inserted, launch "DrvInst.exe" in the folder .. \ Program Files (x86) \ WPulsePen or manually reinstall the USB drivers that are contained in the folder "wRs Usb Driver" if the problem has not been solved with the previous suggestions.

- **fig.1 - icon 6 green and icon 5 red:** the wRs1 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.
- **fig.1 - icons 5 e 6 both green but icons 12 (red and blue) inactive:** the wEc1 / wTn1 units do not connect.
 - Check that the wEc1 / wTn1 units are turned on (acoustic signal at power on).
 - It is necessary that the radio channel of all units wRs1, wEc1, wTn1 is the same and that the relative firmware are compatible: go to the "settings" panel of the software (fig. 1 - icon 3), select the programming mode and follow the instructions in the online Help of the software to put the involved wRs1, wEc1, wTn1 units in programming mode, one at a time, in order to verify and eventually update what is required. Contact DiaTecne s.r.l. in case of doubts or problems.
- **fig.1 - icons 5 e 6 both green and icons 12 (red and blue) active:** the system is in "Freeze" mode due to the absence of tonometric signal on the wTn1 probe - sensor 2 (blue trace).
 - Gently touch the tonometric sensor with your fingers.

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.

21. Mutual interference with other systems

The PulsePen device has been designed to be immune to electrical, electromagnetic, electrostatic and magnetic disturbances, normally present; similarly, the PulsePen 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. Considering the "Intended use" of the device that requires a qualified medical / nurse operator, the latter can easily recognize an abnormal operating situation, such as the presence of "noise" superimposed to the signal or alteration of the morphology of the signal and follow the instructions suggested above.

Typical sources of disturbance are "hotspots" / WiFi devices, Bluetooth / Zigbee devices, cell phones and any type of transmitter in the 2.4 GHz frequency band.

- Electromedical devices require special precautions for electromagnetic disturbances (EMC) and must be installed in accordance with the information in the following tables.
- Mobile radio frequency communication devices can disturb electromedical devices.
- For the correct functioning of the PulsePen device, the wEc1 and wTn1 units must be within a radius of 3 meters from the wRs1 unit. Greater distances may cause incorrect operation.
- The use of cables and accessories other than those supplied could adversely affect the performance of the device.
- During use, no other devices should be connected to the patient and should be more than 15 cm away from the patient, the PulsePen and patient cables.

22. Technical Specifications

General

Capture	16 bit
Sampling Frequency	1000 S/sec
Wireless	ISM @ 2.4 GHz
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.

wRs1

PC connection	USB 1.0 / 2.0 - type A
Data transmission	ISM band 2.4 GHz, modulation MSK, ERP = 2 dBm (P \approx 1.6 mW)
LED	Operating mode signaling
Power supply	< 50 mA @ 5V, powered by the USB connector of the P.C.
Weight	12 g
Dimensions [mm]	67 (L) x 25 (W) x 11 (H)
Material	Bayblend FR3010

wEc1

Resolution	0.15 μ V
Dynamic range	$\geq \pm 5$ mV
Data transmission	ISM band 2.4 GHz, modulation MSK, ERP = 2 dBm (P \approx 1.6 mW)
Acoustic Signals	Power on / off
Power supply	Alkaline battery AAA - 1.5V IEC LR03 (indicative autonomy \geq 50 hours / \geq 600 exams)
Vibrations	≤ 20 g @ 10 Hz - 2 KHz sinusoidal
Shock	≤ 150 g
Weight	36 g without battery
Dimensions [mm]	49 (L) x 75 (W) x 21 (H)
Material	Bayblend FR3010

wTn1

Resolution	0.004 mmHg
Dynamic range	≥ 220 mmHg
Data transmission	ISM band 2.4 GHz, modulation MSK, ERP = 2 dBm (P \approx 1.6 mW).
Acoustic Signals	Power on / off
Power supply	Alkaline battery AAA - 1.5V IEC LR03 (indicative autonomy \geq 50 hours / \geq 600 exams)
Max force to the sensor	4.5 Kg
Vibrations	≤ 20 g @ 10 Hz - 2 KHz sinusoidal
Shock	≤ 150 g
Weight	25 g without battery
Dimensions [mm]	114 (L) x 25 (W) x 20 (H)
Material	Bayblend FR3010

CV010

Terminals	Universal for tab, clip ECG electrodes
Connectors	DIN 42802 compliant
Material	TPE + PA

Batteries:

The technical characteristics that the batteries must meet in order to be used with the wEc1 and wTn1 units are fully specified with the abbreviation "AAA - Alkaline 1.5 V - IEC LR03".

- "AAA" is the code that identifies the size of the batteries, 10.5 x 44.5 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 LR03" is the IEC coding equivalent to "AAA - Alkaline"

ECG Electrodes:

The wEc1 unit and the CV010 cable set of the PulsePen MD must be used in combination with "disposable" ECG electrodes in order to perform their function. These electrodes must be provided by the user. The ECG electrodes are in turn a Medical Device and to work properly with the wEc1 unit, they must meet the following characteristics:

Specifications:

Type	Disposable
Connection	Direct with Crocodile - Tab or Clip
Material	Conductor Ag/AgCl
Gel	Pre-gelled with solid state biocompatible medical adhesive gel
Max impedance @10 Hz	3 K Ω
Max Offset	100 mV
Dimensions	There are no particular size constraints
Certification	Medical Device certified according to 93/42/EEC MDD or MDR

Sphygmomanometer:

The sphygmomanometer is a medical device that must be provided by the user.

Its use is not strictly necessary for the Pulse Pen to fulfill its intended use, which is evaluating the stiffness of the arteries using the "Applanation Tonometry" method. However measurements taken with the sphygmomanometer allow you to complete the analysis of the pressure wave by providing additional parameters.

The Systolic and Diastolic values measured with the sphygmomanometer must be entered manually by the user of the PulsePen software.

Specifications

Type	Manual or Automatic
Certification	Medical Device certified according to 93/42/EEC MDD or MDR

Computer:

The software that is part of the MD PulsePen 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 wRs1 unit can be inserted during operation.

The wireless transmission between the wRs1 unit and the units with applied parts wEc1 and wTn1, make the computer galvanically isolated from the patient.

Specifications

Clock Frequency	≥ 2GHz
Ram	≥ 2 GB
Free Hard Disk space	≥ 4.5 GB (SW + Database)
Graphic Resolution	≥ 1280 x 800, 24 bit color
Operating System	Windows [®] XP SP2/3, Vista, 7, 8, 10 - 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.
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).

The computer running the software must work in "stand alone" mode, i.e. independently from other processing units and from wired or wireless data networks, including WiFi, ZigBee, ...

To prevent unauthorized access to patient personal data (name, surname, date of birth, exams), it is mandatory:

- Use a login password, which is required both at startup and when returning from "sleep" mode.
- Press the "Windows + L" keys to immediately activate the "sleep" mode when you leave your workstation.
- Set the automatic "sleep" mode within 2-5 minutes of not using the keyboard and mouse.

Install an antivirus software.

The data exchanged between the computer and the wRs1 unit and the data exchanged wirelessly between the wRs1, wEc1 and wTn1 units that make up the PulsePen medical device, are encrypted with a key that is updated each time the software is restarted.

The software manages the patient database by storing personal data and exams in binary code that cannot be interpreted unless it has the necessary information, property of DiaTecne. The user can make a backup

of the patient database at any time while the software automatically creates a backup of the patient database every 7 days, keeping the last 5 backups and deleting the oldest.

For the exchange of exams between different working groups, a “privacy” export mode has been implemented, whereby the names / surnames of patients are replaced by their initials. It is also possible to select only the exams related to the type of artery desired (Carotid, Femoral, Brachial, ...).

In case of updating the operating system after the first installation of the software of this MD, make sure it is included among those listed in the previous table.

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.

23. 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 from wEc1 / wTn1 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 sensor of wTn1 or other units because this could cause serious problems, irreparably damaging the internal parts.
- CV010 patient cables are thin and flexible for improved handling. It is necessary to avoid both tugging and bending them at a sharp angle so as not to damage them.
- This device is intended exclusively for professional users such as doctors / nurses who are familiar with the “applanation tonometry” method, in medical clinic or research centers.
- 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.
- The processing of the recorded data and the diagnosis are exclusive to the doctor.
- The acquired ECG lead is used exclusively for the calculation of PWV and should not be used to make any type of diagnosis on the patient.
- Do not sterilize the device either in an autoclave or with liquid substances.
- Do not subject the tonometric sensor of the wTn1 probe to mechanical shocks such as bumps or falls.
- Keep the wTn1 and wEc1 units, with its patient cable, at a distance from the computer no less than 1.5 meters and the computer itself at a distance of no less than 1.5 m from the patient.
- Avoid touching any part of the computer at the same time, including the wRs1 unit, and one or both units wEc1 (with its patient cable) and wTn1.
- Do not immerse any part of the device in water or other substances or subject it to splashes. Never use Gel on the sensor of wTn1.
- Do not carry out maintenance on the device that involves opening it; in case of device malfunction contact DiaTecne s.r.l.

- If there are any abrasions, breaks in the sheath or any defect in the CV010 patient cable, use of the device must be immediately suspended and the defective part sent to DiaTecne s.r.l. for repair / replacement.
- 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 wTn1 tonometric probe and the CV010 patient cable terminals 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.
- During the examination, keep the wEc1 unit at least 20 cm from the patient and operator and limit the duration of contact of the wTn1 unit with the patient and operator to the time necessary to perform the exam: all this to reduce electromagnetic radiation exposure due to the transmission of signals via radio, even if they are of very low intensity.
- Do not turn on or use the device if the battery compartment caps are not properly closed.
- Connect the CV010 patient cable connectors only to the corresponding sockets of the wEc1 unit. Do not make any different types of connections to these connectors.
- The device must never be used together with a defibrillator as it was not designed for this use.
- During the recording of the carotid pressure curve, compression of the carotid bulbs could accidentally induce a reduction in heart rate. This phenomenon may be more pronounced in elderly patients with accentuated vagal sensitivity. 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 patient archive as described in the software's online Help. 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 PulsePen or alternatively activate the 'airplane mode' on these devices.
- If it is not possible to activate 'airplane mode' on the computer and / or turn off WiFi and Bluetooth, use a USB extender cable to connect the wRs1 unit, in order to keep the latter away from the computer itself.
- In the event of adverse events and / or serious accidents involving the medical 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.

24. Recorded values of Electromagnetic Compatibility



Tab. 1: Reference and Declaration of Manufacturer - Electromagnetic Emissions

The PulsePen is suitable for use in the specified electromagnetic environment. The user of the PulsePen should assure that it is used in an electromagnetic environment as described below.		
Emissions tests	Compliance	Electromagnetic Environment
RF Emissions CISPR 11	Group 1	The PulsePen uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The PulsePen is 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	Not Applicable	
Voltage fluctuations / Flicker Emissions IEC 61000-3-3	Not Applicable	



Tab. 2: Reference and Declaration of Manufacturer - Electromagnetic Immunity

The PulsePen is suitable for use in the specified electromagnetic environment. The user of the PulsePen should assure that it is used in an electromagnetic environment as described below.			
Immunity Test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 8KV contact +/- 2KV, +/- 4KV, +/- 8KV, +/- 15KV air	+/- 8KV contact +/- 2KV, +/- 4KV, +/- 8KV, +/- 15KV 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 Frequency 100 kHz	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 0.5KV, +/- 1KV differential mode +/- 0.5KV, +/- 1KV, +/- 2KV common mode	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short Interruptions and Voltage variations on power supply input lines IEC 61000-4-11	Voltage dips 0% U_T , 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T , 1 cycle / 70% U_T , 25/30 cycles, Single phase @ 0° Voltage interruptions 0% U_T , 250/300 cycles	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PulsePen requires continued operation during power mains interruptions, it is recommended that the computer used with the PulsePen be powered from an uninterruptible power supply or a battery.
Magnetic Field at Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Tab. 3: Reference and Declaration of Manufacturer - Electromagnetic Immunity

The PulsePen is suitable for use in the specified electromagnetic environment. The user of the PulsePen should assure that it is used in an electromagnetic environment as described below.			
Immunity Test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic Environment
Conducted RF EN 61000-4-6	<p>from 150 kHz to 80 MHz</p> <p>Home Healthcare Environment 3 V RMS outside the ISM band, 6 V RMS in the ISM and amateur radio bands</p> <p>Professional Healthcare Environment 3 V RMS outside the ISM band, 6 V RMS in the ISM band</p>	Not applicable	<p>Portable and mobile RF communications equipment should be used no closer to any part of the PulsePen, including cables, than the minimum recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> <p>$d = 1,2\sqrt{P}$ 150kHz to 80 MHz</p> <p>$d = 1,2\sqrt{P}$ 80MHz to 800 MHz</p> <p>$d = 2,3\sqrt{P}$ 800MHz to 2,5GHz</p> <p>Where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths for fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Levels characteristic of a typical commercial / hospital environment.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF EN 61000-4-3	<p>3 V/m 80 MHz to 2,7 GHz</p> <p>80% AM at 1kHz</p>	<p>3 V/m 80 MHz to 2.7 GHz</p> <p>80% AM at 1kHz</p>	<p>Field strengths for fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Levels characteristic of a typical commercial / hospital environment.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

Tab. 4: Recommended separation distances between portable / mobile RF communications equipment and the PulsePen

The PulsePen is intended to be used in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the PulsePen can help prevent electromagnetic interference by maintaining a minimum distance between portable / mobile RF communication equipments (transmitters) and the PulsePen as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of the transmitter (W)	Separation distance according to frequency of transmitter m (meters)		
	from 150 kHz to 80 MHz $d = 1.2 P$	from 80 MHz to 800 MHz $d = 1.2 P$	from 800 MHz to 2.5 GHz $d = 2.3 P$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at the maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated from the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
 <i>at 80MHz and 800MHz, the separation distance for the higher frequency range applies.</i>			
 <i>These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</i>			

25. 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 medical device can be stored without being used) is declared as a precaution equal to 10 years from the date of manufacture.

26. 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.

27. Symbols and Abbreviations



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



Manufacturer's Data



Medical Device



CE conformity Mark

The code of the Notified Body is next to the symbol

0051

Identification code of the Notified Body - IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.



Model



Identification symbol of the medical device configuration - Product Code



Serial number identification symbol



Applied parts are of type BF



Insulation Class II



The device incorporates radio frequency transmitters (not ionizing radiations)



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

28. Labels

The label with the identification data is located on the underside of the case.

PulsePen device label example, code **WPP001-ET**, produced on 01.12.2022,
Serial Number 2200B, placed on the device case.
UDI-DI WPP001-ET = 08059388230013



PulsePen device label example, code **WPP001-ETT**, produced on 01.12.2022,
Serial Number 2200F, placed on the device case.
UDI-DI WPP001-ETT = 08059388230020



Each part of the MD, in order to be identified, also has a label showing its code (wRs1, wEc1, wTn1, CV010, WPulsePen) together with the serial number:

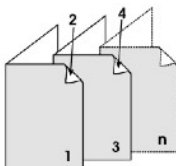



29. Various

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 PulsePen device, without prior notice, notifying the competent authorities only.