

User Manual

PulsePen device is manufactured by DiaTecne s.r.l.

 $m{\Delta}$ This manual is an integral part of the product and must be kept together with it.

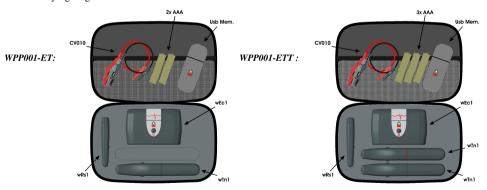
Composition:

The PulsePen device, cod. WPP001-ET / WPP001-ETT includes the following parts:

- Tonometric Unit **PulsePen**, code wTn1, for the capture of a pressure signal with the non-invasive "applanation tonometry" method and radio transmission to the wRs1 Unit. The number of such units included in the package is one for the WPP001-ET device and two for the WPP001-ETT device.
- ECG Unit, cod. wEc1, for one ECG lead capture and radio transmission to the wRs1 Unit.
- Signal receiver Unit, cod. wRs1, to be inserted in a Usb port of the computer, for synchronization and signals collection.
- 2 ECG cables with crocodile terminals, cod. CV010.

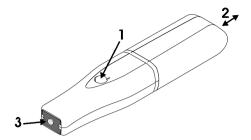
Generic accessories:

- Usb memory with Software, Tutorial, this manual in pdf format
- Two 1.5 V AAA IEC LR03 Alkaline batteries
- Guarantee Certificate
- Carrying Bag



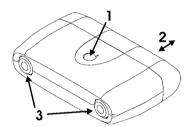
Note: the PulsePen works with a computer, supplied by the user, in order to display and save signals. The computer connection is galvanically isolated due to the radio link with the wRs1 unit. During patient examination is moreover necessary to insert the systolic and diastolic pressure values measured with a validated sphygmomanometer supplied by the user.

Tonometric Unit wTn1:



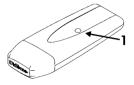
- 1. On / Off button: keep pressed for about 1 sec.
- Cap for battery replacement: pull away from the tonometer's body. Extract the old battery pushing it from the opposite side of the opening. Insert the new fresh battery never forcing and following the specified polarity. Reinsert the cap in its final position pushing it until snap occurs.
- 3. Active part of the tonometric sensor.

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. Extract the old battery. Insert the new fresh battery never forcing and following the specified polarity. Reinsert the cap in its final position pushing it until snap occurs.
- 3. Patient cables connectors.

Signal Receiver Unit wRs1:



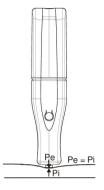
Led signalling the operating mode. This Led blinks green when the software is not running or in
case the device is not correctly installed. This Led is fixed green during normal operations while
it's red during reprogramming / update.

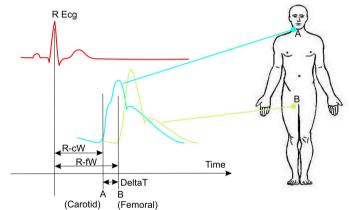
Intended use:

In this manual, when writing about device or equipment, the reference is to all its parts, unless otherwise noted. Each unit alone does not produce useful results.

This device is intended to be exclusively used by medical / paramedical personnel. Pls keep in mind that morphology and quality of the pressure signal acquired by not skilled people could give erroneous signal interpretation.

The primary functions are capture, display and storage of the arterial tonometric signal in order to later proceed to the calculation of the related parameters and of the Pulse Wave Velocity - PWV, that defines the arterial stiffness. This instrument is based on the applanation tonometry principle. According to this method, the sensor is placed over the skin were the artery is found, applying a moderate pressure; in this way the artery comes slightly compressed (applanation tonometry) with a balance of the circumferential forces inside the vessel. In this way the sensor records the pressure in the middle of the compressed artery. Intermediate layers between sensor and vessel, with their thickness and rigidity, that change for each individual case, influence the pressure measured by the sensor in a not, a priori, quantifiable manner. For this reason it is necessary to calibrate tonometric signals using an external sphygmomanometer (supplied by the operator) in order to assess the systolic and diastolic pressures. The calibration process is based on the assumption that diastolic and mean pressures substantially don't change along the arterial tree.





The pulse wave velocity is defined as the propagation velocity of the pressure wave from the center to the periphery and is therefore obtained by dividing the distance between two examined points (for example Carotid and Femoral) by the related sphygmic wave transit time (DeltaT).

This propagation time can be assessed in two different ways:

- A) By using the wEc1 unit in association with the wTn1 unit in order to measure the delay time between the ECG-R wave and the "foot" of the tonometric wave, first in Carotid (R-cW) and after in the peripheral artery under examination (for example the Femoral Artery according to the figure, R-fW) and obtaining the difference, DeltaT.
- B) By using two wTn1 units to contemporary capture two tonometric signals, one of them in Carotid and the other in the selected peripheral Artery, obtaining the time interval DeltaT between the two wave's "feet".

The ECG lead captured must only be used for PWV determination and never must be used for a diagnosis on the patient!

Technical Specifications:

wTn1:

On / Off button

Resolution: 0.004 mmHg Dynamic range: ≥ 220 mmHg

Capture: 16 bit @ 1000 S/sec

Data Rx / Tx: radio link, ISM 2.4 GHz Acoustic signal: On/Off switching

Power supply: Alkaline AAA - 1.5V IEC LR03

battery

Max applicable sensor force: 5.5 Kg

Vibrations: $\leq 20 \text{ g} @ 0 \div 2 \text{ KHz sinusoidal}$

Shock: $\leq 150 \text{ g}$

Weight: 25g without battery

Dimensions [mm]: 114 (L) x 25 (W) x 20 (H)

wEc1:

On / Off button

Resolution: $0.15 \mu V$ Dynamic range: $\geq \pm 4.5 \text{ mV}$

Capture: 16 bit @ 1000 S/sec

Data Rx / Tx: radio link, ISM 2.4 GHz Acoustic signal: On/Off switching

Power supply: Alkaline AAA - 1.5V IEC LR03

battery

Vibrations: ≤ 20 g @ $0 \div 2$ KHz sinusoidal

Weight: 37g without battery

Dimensions [mm]: 49 (L) x 75 (W) x 21 (H)

wRs1:

P.C. Connection: USB

Power supply: powered by P.C. connector

Led: operating mode signalling

Data Rx / Tx: radio link, ISM 2.4 GHz

Weight: 11g

Dimensions [mm]: 67 (L) x 25 (W) x 11 (H)

General:

Approximate autonomy: 50h

Ambient temperature: 5 ÷ 40 °C

Relative humidity: 30% ÷ 80% non condensing

Atmospheric pressure: 860 ÷ 1060 hPa

CV010:

Universal terminals for tab, clip, press-stud

electrodes.

Connectors DIN 42802 compliant

Computer:

Processor clock frequency ≥ 2GHz

Ram memory ≥ 2 GB

Free Hard Disk space ≥200 MB

Graphical resolution ≥ 1280 x 800, 256 colours Operating system: Windows[®] XP SP2..., Vista,

Windows® 7, Windows® 8 - 32/64 bit

Free USB ports: 1 IEC 60950-1 compliant

Classification:

Class IIa medical device according to the Directive 93/42/CE

Computer Connection:

Connection of the *WPP001-ET/ WPP001-ETT* device to the computer occurs through the *wRS1* unit by inserting it in one USB port:

Software Installation:

Insert the included Usb memory drive in the computer port.

- Pls wait the end of the following procedure before inserting the wRSI unit in one Usb port!
- Launch Setup.exe: the WPulsePen_LP SW will be installed creating a desktop icon together with the wRS1 Usb drivers.
- Upon finishing installation, insert the *wRS1* unit in the Usb port and wait for the correct device identification. In case of problems, manually reinstall the drivers that are in the following folder: wRs Usb Driver
- Run the software **WPulsePen LP**. The associated software release is WPP001LP-ETT- 1.1.0.

Use of the device:

Insert the *wRSI* receiver in one Usb port and wait for device recognition. Extract the cap from the *wEc1* and *wTn1* units, insert batteries into the battery compartment strictly following the indicated polarity (see pg 2) and reinsert the cap.

⚠ Use only 1.5V IEC LR03 – AAA Alkaline batteries.

Note: dead batteries must be disposed of in the special containers, since they are high-pollution wastes!

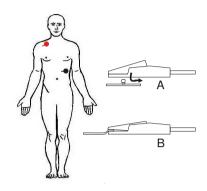
Using fresh disposable ECG electrodes Ag/AgCl with incorporated gel, to be used for crocodile clips, position them as follows:

R (red): subclavian right region

B (black): subcostal left region

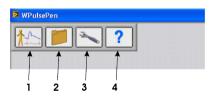
The suggested position can be modified according to the operator opinion when altered ECG signals are present, for example in case of pathologies. Direct electrodes contact with synthetic dresses must be avoided because it's cause of superimposed noise; in this case it's useful to interpose one sheet of paper.

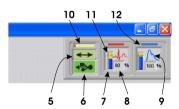
Connect patient cable crocodiles to related electrodes according to their type (type A or type B, see figure at side) and insert connectors from the other side in the corresponding *wEc1* sockets.



Start the Software **WPulsePen_LP** on the Computer.

Switch on the *wEc1* / *wTn1* unit by keeping pressed the on/off key until the acoustic signalling (about 1 sec). Such signal ends with a single "beep" in case of *wEc1* or *wTn1* programmed as Sensor1 (red trace) while ends with two "beeps" in case of *wTn1* programmed as Sensor2 (blue trace).



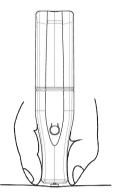


- 1. Key for the patient selection in order to start a new examination
- 2. Key to archive access.
- 3. Setup key and device programming.
- 4. On line Help Key.
- 5. Indicator of correct data exchange with the wRs1 receiver (green).
- 6. Indicator of wRs1 Usb device recognized (green).
- 7. Graphical battery gauge
- 8. Numeric battery gauge: in case of less then 10% indication, the battery must be replaced.
- Icon for Ecg or Tonometric active sensor.
- 10. Bar that shows data from Usb adapter waiting for processing: shorter it means higher computer speed.
- 11. The positive battery terminal becomes yellow during standby, i.e. when "Freeze" is active or during screens different from signals capture.
- 12. Sensor 1 corresponds to the red signal (Ecg or Tonometer) while sensor 2 corresponds to the blue signal (only Tonometer).

Select the Patient icon and insert information as name, surname, birth date, gender: at this point the keys corresponding to the Arteries will be enabled. Choosing one of them a new window will be opened. Place the **PulsePen** probe on the region of interest: captured signals will be displayed on the computer screen. An automatic freeze function, stops the signal capture in case of no activity on Sensor 2 (blue trace).

In order to obtain good quality tonometric signals, the patient must be lying down on the bed while the operator's elbow must firmly lye on a surface and the probe's handle is near the sensor in such a way that operator's fingers touch the patient's skin, reducing in this way tremors (see figure). The probe must be kept perpendicular and not tilted.

Once a good quality signal has been captured of the required duration, the hard disk storage is enabled by pressing the icon with the diskette symbol (or the Enter key): a new window will be displayed in order to insert systolic and diastolic pressures captured by an external sphygmomanometer. In case of peripheral artery, also distance values are required, measured in millimetres: they are three and are related to Carotid-Peripheral Artery, Carotid - Suprasternal Notch and Suprasternal Notch - Peripheral Artery: in this way during the PWV assessment it's possible to apply both methods for the distance evaluation, i.e the direct method (direct distance multiplied by 0.8) and the subtractive one.



The WPulsePen_LP software storage is in text format file (*.txt) in the subfolder "ASCII" of the WPulsePen_Data folder. The initial part of the file contains patient data, the explored artery (Car Carotid, Fem Femoral, ...), examination's date/hour, systolic and diastolic pressure values and distances between capture points manually inserted by the operator and after that, two columns with signal samples of the two sensors (Ecg + Tonometer or two Tonometers).

Selecting the Archive icon, all the examinations are shown and it's possible to choose which one to display on the screen.

The Setup icon allows to select language, date format, ..., while the Help icon opens a window with the on line instructions (pls refer to this online help for updated operating instructions).

In order to switch off the sensors, keep pressed the on/off key until the acoustic signalling (about 1 sec).

Activation of **wEc1** and **wTn1** units is shown on the computer screen (points 7, 8, 9, 11, 12) of the previous image, as the battery level and the active/standby state. Closing the program, automatically switches off the **wEc1** e **wTn1** units: it also occurs in case of no connection with the **wRs1** units for more than 30 sec. The last situation takes place also when the software WPP001LP-ETT is not executing: **wEc1** e **wTn1** units wait for connection with the **wRs1** unit without transmitting data.

Maintenance and cleaning:

No particular periodic maintenance or calibration operations are necessary on the instrument.

⚠ In the case of prolonged non-use, remove the batteries.

Before use, the metallic disc of the **PulsePen** probe, the patient cable and the probe's case must be cleaned, using a clean, dry cloth or dampened with a small quantity of alcohol. Pay attention especially to the probe's plunger avoiding mechanical stresses.

Mote: be very careful to keep the alcohol or other liquids from penetrating into the PulsePen probe or into the other units because this could cause serious problems, irreparably damaging internal parts!

The PulsePen Ecg cables are very thin and flexible in order to be easy to handle. One must avoid pulling, and bending them at a right angle so as not to damage them.

Marnings and precautions for use:

- This instrument is intended to be used only by medical/paramedical personnel in medical
- Do not use in the operating room, or in any case where there are inflammable gases/substances.
- Do not use for intra cardiac applications or at direct contact with internal body parts.
- Data elaboration must be performed by the doctor through dedicated software.
- Do not sterilize either in autoclave neither with liquid substances.
- Do not submit the pressure plunger of the tonometric unit wTn1 to mechanical shocks as impacts or falls.
- Regularly clean the disc of the tonometric probe wTn1, the terminals of the patient cable CV010 and the case after each use, as indicated in the previous paragraph.
- Keep the wTn1 and wEc1 units with the related patient cable at a distance of no less than 1.5 meters from the computer and the same computer at no less than 1.5 meters from the patient.
- Avoid touching simultaneously any part of the computer included the wRs1 unit and one or both the **wEc1** unit, included the patient cable, and **wTn1**.
- Do not immerse any part of the device into water or other substances, or expose it to sprays. Never use Gel on the pressure sensor of wTn1!
- Do not carry out any maintenance work on the device opening it; in the case of malfunctioning of the device, contact DiaTecne s.r.l.
- If any abrasions, sheath tears, or any kind of defects appear in the patient cable CV010, immediately suspend use of the device and send the defective part to Diatecne s.r.l. for repair/replacement.
- Do not use the device in case of breakage of the case, do not try to repair it but contact Diatecne s.r.l. for repair/replacement.
- Do not make changes of any kind to the device.
- Keep the tonometric probe wTn1 and patient cable terminals away from electrical outlets and surfaces where there may be potentially dangerous voltages.
- Use a battery-powered (portable) computer or, alternatively, an AC-powered computer, medical regulations in force compliant.
- Use the device at a safe distance from sources of electromagnetic disturbance such as cordless telephones operating at radio frequency/cellular phones, Bluetooth devices and WiFi or other equipment emitting high frequency electromagnetic waves.
- During examination keep the wEc1 unit at a distance at least of 20 cm from the patient and operator and limit the duration of contact of the wTn1 unit with patient and operator for the time required for the examination: this is in order to reduce the exposure time to the electromagnetic radiations due to radio signal transmission.

- Use only 1.5V batteries of the indicated type, inserting them as stated and checking their condition before each use (dead or damaged batteries may cause leakage of acid).
- Do not switch on or use the device if the cover of the battery compartment is not correctly closed.
- Insert the patient cable CV010 connectors only into the corresponding sockets of the wEc1 unit. Do
 not connect those plugs in any other way.
- The equipment must never be used in situations where a defibrillator is required, since it has not been designed for such use.
- During Carotid pressure signals recording the compression of the Carotid bulbs may accidentally
 produce reduction of heart rate. This kind of phenomenon could be more pronounced in old aged
 patients with accentuate vagal sensitivity. It is highly recommended to stop the examination upon
 appearance of bradycardia. We furthermore remember that is absolutely to avoid simultaneous
 compression of Carotid bulbs, considering that this can cause syncope by arterial hypotension and
 severe bradyarrhythmias.
- Install an antivirus software on the computer used for the capture of the signals coming from the
 device.
- Reduce the probability of radio interference following prescription of the next paragraph.
- Use the equipment only for the purposes stated in this manual.
- DiaTecne s.r.l. will not be held responsible for any damages caused to persons, animals, or things
 if the user does not scrupulously follows the indications given in this manual.

Reciprocal interferences with other equipments:

The **PulsePen** device was designed to be immune to electrical, electromagnetic, electrostatic and magnetic disturbances that are normally present; likewise, the **PulsePen** produces a small amount of disturbances for other equipments. It cannot, however, be excluded that, in particular situations, some functioning anomalies could appear also in the form of signal alteration; in this case it is necessary, when possible, to move away all potential sources of disturbance, or to move to a more appropriate location.

Considering the intended use of the device that requires a medical qualified operator, he/she may easily recognize any anomalous functioning situation, such as, for example, the presence of "noise" superimposed to the signal or alteration of the morphology, and follow the indications suggested here.

Typical noise sources are the "hotspot"/WiFi devices, Bluetooth devices / Zigbee devices and any kind of transmitter in the 2,4 GHz frequency band.

A Ensure that the WiFi / Bluetooth functions of the computer and cellular phones, are switched off during the use of the apparatus. When available, activate the 'aero mode' on this devices.

- Medical devices require special cautions for electromagnetic disturbances (EMC) and must be installed according to instructions in the following tables 1 ÷ 4.
- Mobile devices for radio frequency communications may disturb electromedical devices.
- For the correct use of the **PulsePen** device, the wEc1 and wTn1 units must be in a 3 meters radius from the wRs1 unit. Higher distances could influence the correct operation.
- The use of cables and accessories different from those in the original package could adversely influence the performances of the device.
- Respect distances from other devices according to table 4.
- The PulsePen device transmits radiofrequency in the ISM 2.4 GHz band with MSK modulation, ERP = 2 dBm.

Table 1: Electromagnetic emissions:

The PulsePen is suitable for use in the specified electromagnetic environment. The purchaser or 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 PulsePer 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	

Table 2: Electromagnetic immunity:

The PulsePen is suitable for use in the specified electromagnetic environment. The purchaser or 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	±6 KV contact ±8 KV air	IEC 60601-1-2 Test level	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Transient/Burst sup IEC 61000-4-4 ±1	±2 KV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	±1 KV for input/output lines > 3 m		
Surge IEC 61000-4-5	±1 KV differential mode	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	±2 KV common mode		

Voltage dips, short Interruptions and Voltage variations on power supply input lines IEC 61000-4-11	0% U _n for 0.5 cycles 40% U _n for 5 cycles 70% U _n for 25 cycles 0% U _n for 5 s	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.
Power frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	IEC 60601-1-2 Test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3: Electromagnetic immunity:

The **PulsePen** is suitable for use in the specified electromagnetic environment. The purchaser or 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
			Portable and mobile RF communications equipment should be used no closer to any part of the PulsePen, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Radiated RF IEC 61000-4-3	3V/m 80 MHz ÷ 2.5 GHz	3V/m	$d = 1.2 \sqrt{P} 80 \text{ MHz} \div 800 \text{ MHz}$ $d = 2.3 \sqrt{P} 800 \text{ MHz} \div 2.5 \text{ GHz}$
Conducted RF IEC 61000-4-6	3V/m 150 KHz ÷ 80 MHz	Not applicable	$d = 1.2 \sqrt{P}$

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).

Field strengths for fixed RF transmitter, as determined by an electromagnetic site survey, should be less then the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:



Table 4: Recommended separation distances between portable and mobile RF communications equipment and the PulsePen:

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

Rated maximum output power of the transmitter	Separation distance according to frequency of transmitter			
(W)	150 KHz ÷ 80 MHz	800 MHz ÷ 2.5 GHz		
	$d = 1.2 \sqrt{P}$	d = 1.2 √P	$d = 2.3 \sqrt{P}$	
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.

Notes:

- at 80MHz and 800MHz, the separation distance for the higher frequency range applies
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

Problems in use and solutions:

THE DEVICE DOES NOT TURN ON (NO ACOUSTIC SIGNALING):

- Check to see that the battery is of the required type, that is inserted in the right way and that it's not dead.
- Keep the On/Off button pressed until the acoustic signaling (about 1 sec).
- Remove and reinsert the battery.

NO SIGNALS ARRIVE TO THE COMPUTER:

- Check to see that the wEc1 and wTn1 units are turned on and that software icons related to the wRs1 unit
 are both green: in case they are not, close the software, extract and reinsert the wRs1 signal receiver, restart
 the software. In case the problem remains, the Usb drivers reinstallation is suggested.
- Ensure that the Computer Protection software, such as Antivirus, Firewall, etc., does not prevent access to
 external Usb devices.
- Make sure that the system is not in "Freeze" mode due to absence of tonometric signal on the PulsePen probe. Touch the sensor with fingers.
- Check to see that the radio channel of wRs1, wEc1, wTn1 units is the same. Pls refer to the on line help for more details.

If you find it's not possible to solve the listed problems by yourself, or if you have doubts regarding the functioning of the equipment, please contact DiaTecne s.r.l. by e-mail at info@pulsepen.com.
You will receive technical assistance in a short time

Notes on recycling:

DiaTecne is sensitive to environmental issues linked to the production of waste.

The user that wishes to dispose of the apparatus at its life end, should contact DiaTecne s.r.l. and will receive appropriate instructions.

Adequate waste selection before recycling and eco-compatible waste processing contributes to avoiding detrimental effects on nature and on human health, an promotes the reuse and recycling of the material of which the product is made

Please note that inadequate disposal of the product entails the application of the normative sanctions of the country where this should take place.

Symbols and Abbreviations:

Manufacturer information



This symbols states that reading the user manual before using the apparatus is mandatory



Warning: pay attention



Class II device



This symbol advices that applied parts are of BF type



The device incorporates radio transmitters (not ionizing radiations)



The crossed garbage can symbol indicates that, when no longer functional, the product should be disposed of separately from other waste as electronic waste.

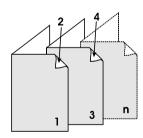
SN: the serial number is on each unit in the format" yyppp": first two digits are for production year, remaining digits are for progressive counting (hexadecimal code).

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Document printing:

In case more printed copies of the document are necessary, open the corresponding "pdf" file with the Adobe Reader program or similar, select options "booklet", "both sides", "left binding", "page size A4", print, fold and bind as shown:



Note: with a view to constant product improvement, Diatecne s.r.l. reserves the right to make any changes it deems necessary, without notice, both to this manual and to the **PulsePen** device, communicating these changes only to the competent bodies!





PulsePen

Ref: WPP001-ET SN:_



