# User Manual
# PulsePen

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

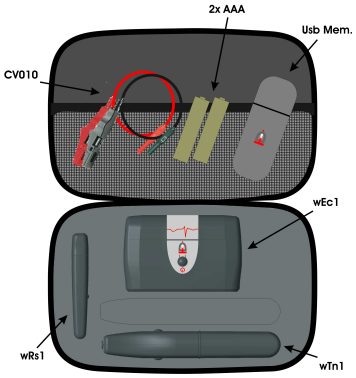
⚠ ***This manual is an integral part of the product and must be kept together with it.***

## Composition

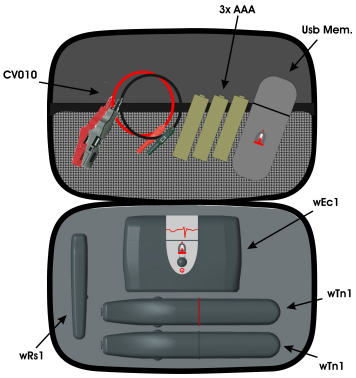
*The PulsePen device, code **WPP001-ET / WPP001-ETT** includes the following parts:*

- Tonometric unit, code **wTn1**, for the capture of a pressure signal with the non-invasive "applanation tonometry" method. 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, code **wEc1**, for one electrocardiographic lead capture.
- Signal receiver unit, code **wRs1**, to be inserted in one USB port of the computer, for synchronization and collection of signals coming from **wTn1** and **wEc1**.
- 2 ECG cables with crocodile terminals, code **CV010**.

Generic accessories:
- USB memory with Software, Tutorial, this manual in pdf format.
- 2 or 3 Alkaline batteries 1.5 V - AAA - IEC LR03, depending on the model.
- Guarantee Certificate.
- Carrying Bag



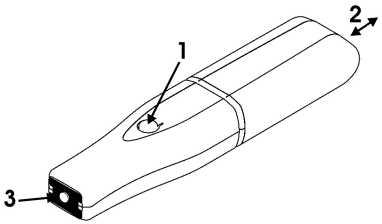

***WPP001-ET***




***WPP001-ETT***

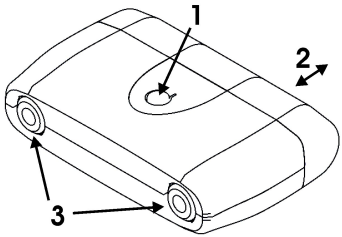
*Note: the PulsePen works with a computer, supplied by the user, in order to display and save signals. The computer connection is galvanically isolated due to the radio link with the **wRs1** unit. Furthermore, during patient examination, it is necessary to input the systolic and diastolic pressure values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

## Tonometric unit: wTn1



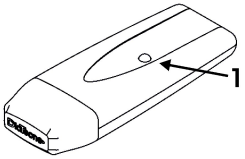

1. On / Off button: keep pressed for about 1 sec.
2. Cap for battery replacement: pull away from the tonometer's body. Push the old battery toward you from the hole on the opposite side of the opening. Gently insert the new fresh battery following the polarity specified on the label. Put the cap on and push it until a snap occurs.
3. The 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. Gently insert the new fresh battery following the polarity specified on the label. Put the cap on and push it until a snap occurs.
3. Patient cable sockets.

## Signal Receiver unit: wRs1

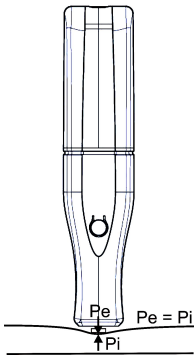



1. LED indicates the operating mode. This LED blinks green when the PulsePen software is not running or if the USB driver is not correctly installed. This LED is fixed green during normal operations while it is red during reprogramming / update.

## Intended Use

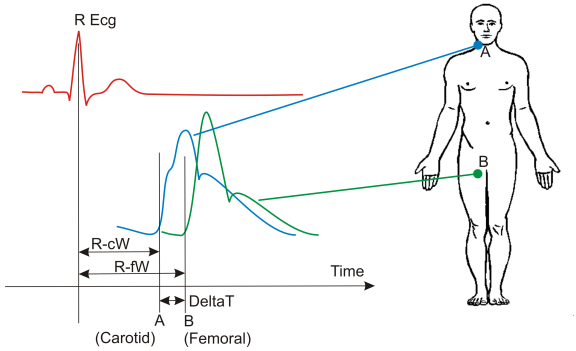
*In this manual, when talking about device or equipment, the reference is to all its parts, unless otherwise noted. Each unit alone does not produce useful results.*

**This medical device is intended to determine the arterial stiffness and to record the arterial pressure wave, by means of the "applanation tonometry", for diagnostic purposes. It must be used by qualified medical / paramedical personnel, familiar with the "applanation tonometry" method, in a medical environment or research centers.**




The primary functions are capture, display, and storage of the arterial tonometric signal for later calculation of the related parameters including Pulse Wave Velocity - PWV, which defines the arterial stiffness. This instrument is based on the applanation tonometry principle. The user places the sensor on the skin, where the artery pulse is found, with a moderate pressure that slightly compresses the artery (applanation tonometry): in such a way, a balance of the circumferential forces inside the vessel is obtained and the sensor records the pressure inside the compressed artery. Intermediate layers between sensor and vessel, with their thickness and rigidity, that vary for each individual, influence the pressure measured by the sensor in a not, a priori, quantifiable manner. For this reason, it is necessary to calibrate the tonometric signals using the systolic and diastolic pressures obtained from an external sphygmomanometer (supplied by the operator). The calibration process is based on the assumption that diastolic and mean pressure substantially don't change along the arterial tree.

*The pulse wave velocity is defined as the propagation velocity of the pressure wave (not of the blood) 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 (I or II):

I. Using the **wEc1** unit together with the **wTn1** unit, first for Carotid (R-cW) and then for the peripheral artery (e.g. the Femoral Artery in the figure, R-fW ), to measure the delay time between the R peak of the ECG wave and the "foot" of the tonometric waves, time A and B, and then the difference between them, DeltaT.

II. Using two **wTn1** units to contemporarily capture two tonometric signals, one of the Carotid and the other of the selected peripheral Artery, to obtain the time interval DeltaT between the two waves' "feet".

⚠ ***The ECG lead captured must only be used for PWV estimation and must never be used for any kind of diagnosis on the patient!***

## Technical Specifications

| | |
|---|---|
| **wTn1:**<br>On / Off button<br>Resolution: 0.004 mmHg<br>Dynamic range: ≥ 220 mmHg<br>Capture : 16 bit @ 1000 S/sec<br>Data Rx / Tx: radio link, ISM 2.4 GHz<br>Acoustic signal: On/Off switching<br>Power supply: Alkaline AAA - 1.5V IEC LR03 battery<br>Max applicable sensor force: 4.5 Kg<br>Vibrations: ≤ 20 g @ 10 Hz - 2 KHz sinusoidal<br>Shock: ≤ 150 g<br>Weight: 25g without battery<br>Dimensions [mm]: 114 (L) x 25 (W) x 20 (H) | **wEc1:**<br>On / Off button<br>Resolution: 0.15 µV<br>Dynamic range: ≥ ± 5 mV<br>Capture : 16 bit @ 1000 S/sec<br>Data Rx / Tx: radio link, ISM 2.4 GHz<br>Acoustic signal: On/Off switching<br>Power supply: Alkaline AAA - 1.5V IEC LR03 battery<br>Vibrations: ≤ 20 g @ 10 Hz - 2 KHz sinusoidal<br>Weight: 36g without battery<br>Dimensions [mm]: 49 (L) x 75 (W) x 21 (H) |
| **wRs1:**<br>P.C. Connection : USB 1.0 / 2.0 - type A<br>Power supply: powered by P.C. connector<br>LED: operating mode signaling<br>Data Rx / Tx: radio link, ISM 2.4 GHz<br>Weight: 12g<br>Dimensions [mm]: 67 (L) x 25 (W) x 11 (H) | **CV010:**<br>Universal terminals for tab, clip, press-stud electrodes.<br>Connectors DIN 42802 compliant |
| **General:**<br>Approximate autonomy (wEc1/wTn1): 50h<br>Operating ambient temperature: +5°C to +40°C<br>Transport and storage ambient temperature: -25°C to +70°C<br>Relative humidity: 30 - 80% non condensing<br>Atmospheric pressure: 860 - 1060 hPa | **Computer:**<br>Processor clock frequency ≥ 2GHz<br>Ram memory ≥ 2 GB<br>Free Hard Disk space ≥ 4.5 GB SW + DataBase<br>Graphical resolution ≥ 1280 x 800, 256 colors<br>Operating system: Windows® XP SP2/3, Vista, 7, 8, 10 - 32/64 bit<br>Free USB ports: 1<br>IEC 60950-1 compliant |

## Classification

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

## Computer Connection

**WPP001-ET** and **WPP001-ETT** devices connect to the computer by inserting the **wRS1** unit into one USB 1.0 / 2.0 - type A port:

## Software Installation

The *PulsePen* system includes two software (x.x.x means the version):

- WPulsePen (WPP001-ETT- x.x.x): full-featured software for the capture, display, storage, and analysis of signals with the calculation of parameters. It includes patient database management and works on signals up to 10 ECG/ tonometric complexes. It's also possible to make long-term signal records with CTRL + S. The patient report generated by this software must always be verified by medical staff who is familiar with tonometry. DiaTecne s.r.l. is not responsible for the final diagnosis.
- WPulsePen-LP (WPP001 LP-ETT- x.x.x): software for capture, display and storage of long-term signals. It does not analyze signals or manage the patient database.

In order to install the Software contained in the included USB memory, proceed as described in the file "readme.txt": both software WPulsePen and WPulsePen_LP will be installed with related desktop icons along with the **wRs1** receiver USB driver.

Refer to "Problems during use and solutions" in case of difficulties.
The font "Arial" is required for correct use.

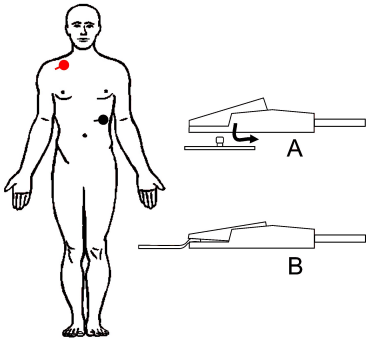
## Use of the device

Insert the **wRS1** receiver in a 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 close the cap.

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

*Note: dead batteries must be discarded in the special containers since they are high-pollution wastes!*

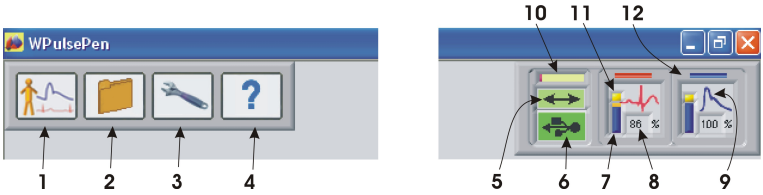
This device requires fresh disposable ECG electrodes Ag/AgCl (incorporated with a gel), that can be used for crocodile clips. Place them as indicated in the figure:
**Red:** subclavian right region
**Black:** subcostal left region




The suggested position can be modified at the operator's discretion when ECG signals are too low, inverted, or altered, for example in the case of pathologies. Direct electrode contact with synthetic dresses must be avoided because it may cause superimposed noises; in this case, it helps to put one sheet of paper in-between.
Connect the crocodiles of the patient cable to the corresponding electrodes according to their types (type A or type B, see figure on the right) and plug the cable from the other side into the corresponding **wEc1** sockets.

Run the Software WPulsePen / WPulsePen_LP and switch on the **wEc1 / wTn1** units by pressing the on/off key until the beep(s) sound (about 1 sec). **wEc1** makes a single "beep", so does **wTn1** when programmed as Sensor1 (red trace), while **wTn1** programmed as Sensor2 (blue trace) makes two "beeps".

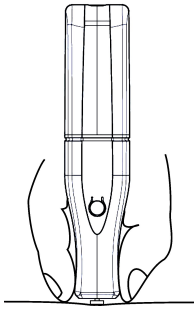
*fig.1*




1. New examination.
2. Patient Archive access.
3. Setup and device programming.
4. Online Help.
5. Data exchange between computer and **wRs1** (green when in normal function).
6. **wRs1** USB unit connection (green when correctly recognized)
7. Graphical battery gauge for **wEc1** and **wTn1**.

8. Battery gauge for **wEc1** and **wTn1**: change the battery when less than 10%.
9. An icon representing the ECG (QRS) or Tonometric (pressure wave) signals depending on the active sensor.
10. Data coming from **wRs1** to be processed: a short bar means better condition compared to a long bar (depends on computer speed, other running programs, …).
11. The positive battery terminal becomes yellow during standby, i.e. when "Freeze" is active or during situations different from run-time signals capture and display.
12. Sensor1 corresponds to the red signal (Ecg or Tonometer) while Sensor2 corresponds to the blue signal (only Tonometer).

The functions described below are related to the WPulsePen Sw, of which the WPulsePen_LP Sw is a simplified version.
Select the "New examination" icon and insert Patient information including 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 **wTn1** probe/s 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 Sensor2 (blue trace).
To obtain good quality tonometric signals, the patient must be lying down on the bed. The operator must keep his/her elbow firmly lying on a stable surface and hold the **wTn1** probe as indicated in the figure below with his/her fingers touching the patient's skin, reducing in such way tremors. The probe must be kept perpendicular to the skin and not tilted. We suggest reading the Quick Guide in the Help-Tutorial. By using the PulsePenHolder, stable signals are obtained without the operator's tremor.
Once a series of superimposable complexes has been captured, when the traffic light on the top-central screen shows green (more info from software Help), the operator can stop the capture lifting the Sensor2. The last 10 cardiac complexes are saved and automatically analyzed by pressing the icon with the diskette symbol or the Enter key. At this point, a new window will be displayed in order to insert systolic and diastolic pressures measured immediately before or afterward by an external sphygmomanometer. In the case of a peripheral artery, the operator should use, in addition, a measuring tape to obtain three distances, in millimeters, between: 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 suggested by the international guidelines, i.e. the "direct" method (direct distance multiplied by 0.8) and the "subtractive" one.

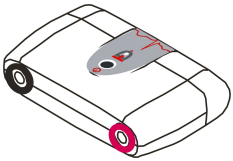
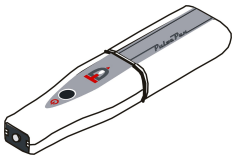


WPulsePen software manages the patient DataBase "WPPArch.dbd" located in the "WPulsePen_Data" folder. Selecting the "Patient Archive" icon, all patients are shown with the related examinations and it's possible to choose which one to display on the screen.
WPulsePen_LP software saves single examinations in text format files (*.txt) in the subfolder "ASCII" of the "WPulsePen_Data" folder.

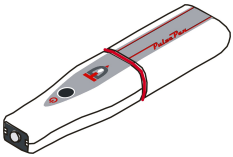
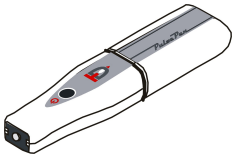
The "Setup" icon allows selecting language, date format, device programming, …, while the "Help" icon opens a window with the software instructions (pls refer to this online Help for updated operating instructions).
Activation of **wEc1** and **wTn1** units is shown on the computer screen (points 7, 8, 9, 11) of the software menu image.
In order to switch off the Sensors **wEc1** and **wTn1**, keep pressing the on/off key until the acoustic signal (about 1 sec). The **wEc1** and **wTn1** units automatically switch off when closing the program or when there is no connection with the **wRs1** unit for more than 30 sec: e.g. when the software WPulsePen / WPulsePen_LP is not executing or the distance between them is too long.
The **wEc1** and **wTn1** units don't transmit radio-frequency until a connection with the **wRs1** unit was established.

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

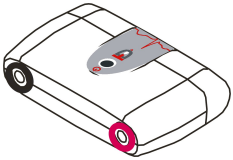
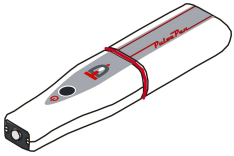
**Allowed Combinations:**
wEc1 - Sensor1 (1 beep at switch on) + wTn1 set as Sensor 2 (2 beeps at switch on). *These are the factory settings for the WPP001-ET system and for the wTn1 unit with a black ring of the WPP001-ETT system*:

[ ✔ ]  + 

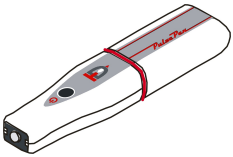
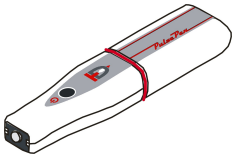
wTn1 set as Sensor 1 (1 beep at switch on) + wTn1 set as Sensor 2 (2 beeps at switch on). *These are the factory settings for the wTn1 units respectively with a red and black ring of the WPP001-ETT system*:

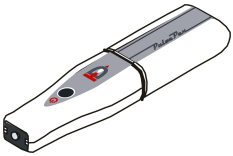
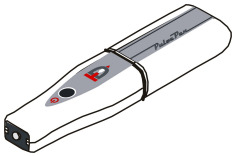
[ ✔ ]  + 

**Wrong Combinations:**
wEc1 - Sensor 1 (1 beep at switch on) + wTn1 set as Sensor 1 (1 beep at switch-on):

[ ✘]  + 

Both the wTn1 modules set as Sensor 1 (1 beep at switch on) or set as Sensor 2 (2 beeps at switch-on):

[ ✘ ]  + 

[ ✘]  + 

## Maintenance and Cleaning

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

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

⚠ ***Before use, the metallic disc of the wTn1 probe, the patient cable CV010, and the probe's case must be cleaned, using a clean, dry cloth or dampened with a small quantity of alcohol.***

⚠ ***Be very careful to keep the alcohol or other liquids from penetrating into the wTn1 probe or into the other units because this could cause serious problems, irreparably damaging internal parts.***

⚠ ***The CV010 Ecg cables are thin and flexible in order to be easily handled. One must avoid pulling or bending them at a sharp angle so as not to damage them.***

## Warnings and Precautions for Use

⚠ ***It is very important to read the following items before the use of the device. Improper use may cause very severe consequences.***

- *This equipment is intended to be used only by medical/paramedical personnel in a medical environment.*
- *Do not use the equipment in the operating room, or in any case where there are inflammable gases/substances.*
- *Do not use the equipment for invasive or 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 neither in autoclave nor with liquid substances.*
- *Avoid mechanical shocks to the pressure plunger of the **wTn1** probe, like collisions or falls.*
- *Regularly clean the disc of the **wTn1** probe, the terminals of the patient cable **CV010,** and the case after each use, as indicated in the "Maintenance and Cleaning".*
- *Keep the units **wTn1** and **wEc1,** with its 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, including the **wRs1** unit, and one or both of the **wEc1**, including the patient cable, and the **wTn1** units.*
- *Do not immerse any part of the device into water or other substances, or expose it to sprays. Absolutely never use Gel on the pressure sensor of **wTn1**.*
- *Do not open the device for any kind of maintenance work; in the case of malfunction of the device, contact DiaTecne s.r.l.*
- *In the case of any abrasion, sheath damage, or any kind of defects appears in the patient cable **CV010**, immediately suspend use of the device and contact Diatecne s.r.l. for repair/replacement.*
- *Do not use the device if breakage occurs to any part, 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 and never use accessories other than those provided.*
- *Keep the tonometric probe **wTn1** and patient cable **CV010** terminals away from electrical outlets/sockets and surfaces where there may be potentially dangerous voltages.*
- *Use a battery-powered (portable) computer or, alternatively, an AC-powered computer, compliant with the current medical regulations.*
- *Use the device at a safe distance from sources of electromagnetic disturbance such as cordless telephones operating at radio frequency/cellular phones, Bluetooth and WiFi devices, or other types of equipment emitting high-frequency electromagnetic waves.*
- *During the examination, keep the **wEc1** unit at a distance of at least 20 cm away from both the patient and operator, limit the duration of contact of the **wTn1** unit with both patient and operator for the time*

*required for the examination: this is to reduce the exposure time to the electromagnetic radiations due to radio signal transmission, although the radio-frequency power is very limited.*

- *Use only 1.5V batteries of the indicated type. Insert them as stated and check their condition before each use (dead or damaged batteries may cause leakage of acid).*
- *Do not switch on or use the device if the covers of the battery compartment are 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 together with a defibrillator since it has not been designed for such use.*
- *During Carotid pressure signal recording, the compression of the Carotid bulbs may accidentally produce a reduction of heart rate. This kind of phenomenon could be more common in old-aged patients with accentuate vagal sensitivity. It is highly recommended to stop the examination upon the appearance of bradycardia. We furthermore remind you that simultaneous compression of both Carotid bulbs is absolutely forbidden, considering that this can cause syncope by arterial hypotension and severe bradyarrhythmias.*
- *Install antivirus software on the computer used for the PulsePen system.*
- *Make backup copies of the patient archive on a regular basis, as described in the software online Help.*
- *Reduce the probability of radio interference following the prescriptions of the next section.*
- ***Use the equipment only for the purposes stated in this manual.***
- ***DiaTecne s.r.l. cannot be held responsible for any damages caused to persons, animals, or things if the user does not scrupulously follow the indications given in this manual.***

## Reciprocal Interferences with other types of Equipment

The PulsePen device was designed to be immune to electrical, electromagnetic, electrostatic, and magnetic disturbances that are present in a normal environment; likewise, the PulsePen produces a small amount of disturbances for other equipment. It cannot, however, be excluded that, in particular situations, some functional anomalies could appear also in the form of signal alteration; in this case, it is necessary to remove all potential sources of disturbance when possible or to move to a more appropriate location.
Considering that the "Intended Use" of the device requires a qualified medical operator, he/she may easily recognize any anomalous functional situation, such as the presence of "noise" superimposed to the signal or alteration of the morphology, and follow the indications suggested above.

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

⚠ ***Ensure that the WiFi / Bluetooth functions of the computer and cellular phones are switched off during the use of the PulsePen. When available activate the 'flight/airplane mode' on these devices.***

- Medical devices require special cautions for electromagnetic disturbances (EMC) and must be installed/ used according to instructions in the following tables.
- Mobile devices for radio frequency communications may disturb electromedical devices.
- For the correct use of the PulsePen, the **wEc1** and **wTn1** units must be within a 3 meters radius from the **wRs1** unit. Higher distance could influence the correct operation.
- The use of cables and accessories different from those in the original package could adversely influence the performance of the device.
- Respect distances from other devices according to the following Tab. 4.
- The PulsePen device transmits radio frequency in the ISM 2.4 GHz band with MSK modulation, ERP = 2 dBm (P ≈ 1.6 mW).
- The PulsePen system meets the requirements of the following tables.

## Tab. 1: 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<br>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<br>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<br>IEC 61000-3-2 | Not Applicable | |
| Voltage fluctuations / Flicker Emissions<br>IEC 61000-3-3 | Not Applicable | |

## Tab. 2: 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)<br>IEC 61000-4-2 | ±8 KV contact<br>±15 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%. |
| Electrical Fast Transient / Burst<br>IEC 61000-4-4 | ±2 KV | Not Applicable | The mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ±1 KV differential mode<br>±2 KV common mode | Not Applicable | The 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 | 0% $U_T$ , 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°<br><br>0% $U_T$ , 1 cycle / 70% $U_T$ , 25/30 cycles , @ 0°<br><br>0% $U_T$ , 250/300 cycles | Not Applicable | The 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 | 30 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. |

## Tab. 3: 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 |
|---|---|---|---|
| Radiated RF IEC 61000-4-3 | 10V/m 80 MHz - 2.7 GHz | 10V/m | Levels characteristic of a typical location in a typical commercial or hospital environment. |
| Conducted RF I.C. 61000-4-6 | 3V 150 KHz - 80 MHz<br><br>6V ISM bands and amateur radio 150 KHz - 80 MHz | Not Applicable | Levels characteristic of a typical location in a typical commercial or hospital environment. |
| Interference may occur in the vicinity of equipment marked with the following symbol:  | | | |

## Tab. 4: Immunity to proximity fields from RF wireless communication equipment

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 equipment (transmitters) and the PulsePen as recommended below, according to the maximum output power of the communications equipment.

| Test Frequency (MHz) | Band (MHz) | Max Power (W) | Distance (m) | Immunity Test Level (V/m) |
|---|---|---|---|---|
| 385 | 380 - 390 | 1.8 | 0.3 | 27 |
| 450 | 430 - 470 | 2 | 0.3 | 28 |
| 710, 745, 780 | 704 - 787 | 0.2 | 0.3 | 9 |
| 810, 870, 930 | 800 - 960 | 2 | 0.3 | 28 |
| 1720, 1845, 1970 | 1700 - 1990 | 2 | 0.3 | 28 |
| 2450 | 2400 - 2570 | 2 | 0.3 | 28 |
| 5240, 5500, 5785 | 5100 - 5800 | 0.2 | 0.3 | 9 |

Minimum separation distances for higher immunity test levels shall be calculated as follows:

$E = (6/d)\sqrt{P}$

Where P is the maximum power (W), d is the minimum separation distance (m), E is the immunity test level (V/m).

## Problems during use and solutions

**The software installation cannot be completed:**

- The software installation requires that the operator has the permissions needed: contact the system administrator in case of problems.

**The wEc1 / wTn1 unit does not turn On ( No acoustic signal):**

- Check if the battery type is the one required, if it is inserted in the right way, and if it's not dead.
- Keep pressed the On/Off button till the acoustic signal (about 1 sec).
- Remove and reinsert the battery.

**No signals arrive at the computer:**

- Verify that the software icons related to the **wRs1** unit (icons 5 and 6 - fig 1) are both green. If the icon related to USB device recognition does not become green (icon 6 - fig 1), close the software, remove and reinsert the signal receiver **wRs1** and restart the software. If the problem remains, it's suggested to verify with the system administrator that access to the USB ports of the computer is not inhibited. Ensure that 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 ..\Programs(x86)\WPulsePen or manually reinstall the USB drivers from the folder "wRs USB Driver" if the problem was not solved with the previous suggestions.
- If both the icons related to the **wRs1** unit are green, check if the **wEc1** and **wTn1** units are turned on and that related software icons (icons 12 - fig 1) are active.
- Make sure that the system is not in "Freeze" mode due to the absence of a tonometric signal on the **wTn1** probe. Gently touch the pressure sensor with your fingers.
- In the "Setup" panel (icon 3 - fig. 1) check if the radio channel of **wRs1, wEc1, wTn1** units is the same. Please refer to the online Help of the software for more details on device programming and parameter setup.

If the problems remain after the above attempts, or if you have doubts regarding the function of the equipment, please contact DiaTecne s.r.l. at the following email address: **info@pulsepen.com**. You will receive technical assistance in a short time.

## Notes on recycling

DiaTecne s.r.l. is sensitive to environmental issues related to the production of waste.

The user that wishes to discard the device at the end of its service life should contact DiaTecne s.r.l. and will receive appropriate instructions.
Adequate waste selection before recycling and eco-compatible waste processing contribute to avoiding detrimental effects on nature and on human health and promote the reuse and recycling of the materials of which the device is made.
Please note that improper disposal of the product may cause sanctions by the Country where this should take place.

## Symbols and Abbreviations


Manufacturer information


It’s mandatory to read the User Manual before using the apparatus


Warning: pay attention


Class II device


Applied parts are of type BF


The device incorporates radio frequency transmitters (not ionizing radiations)


The product must be discarded as electronic waste, separately from other waste, at the end of its service life

SN: each unit is identified with a serial number.

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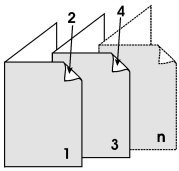
It's possible to print more copies of this document in the following way:

- open the "pdf" file of this manual with Adobe Reader or similar
- select options "booklet", "both sides", "left binding ", "page size A4", "vertical orientation"
- print both sides, fold and bind as shown:




*Note: with the purpose of a continuous 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.*