win-pod

Installing and Using manual

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CE / 0124

Foreword

You are a new MEDICAPTEURS product's owner of and we thank you.

win-pod platform is a high performance system. Such an exceptional quality of results needs to take care of the platform. It's essential to read this manual before using the platform.

win-pod *software* was created to be « User-Friendly » But this argue doesn't avoid you to read the user manual.

Added to this manual, you can find on the "Win-Pod Software" CDRom :

- The "Win-Pod Software" **Quick Easy Guide**
- The platform and software **User Manual**
- The video guide (which helps you to install and use it).
- The **Trouble Shooter**

ENJOY READING THE USER MANUAL AND WELCOME TO THE MEDICAPTEURS PLATFORM USER CLUB

Quality requirements

This product was tested and approved for the Annex VI, section 3 of the Directive 93/42/EEC for Medical Device.
DEKRA Certification GmbH (Identification Number 0124) approved the Quality System used for Products Final Test.

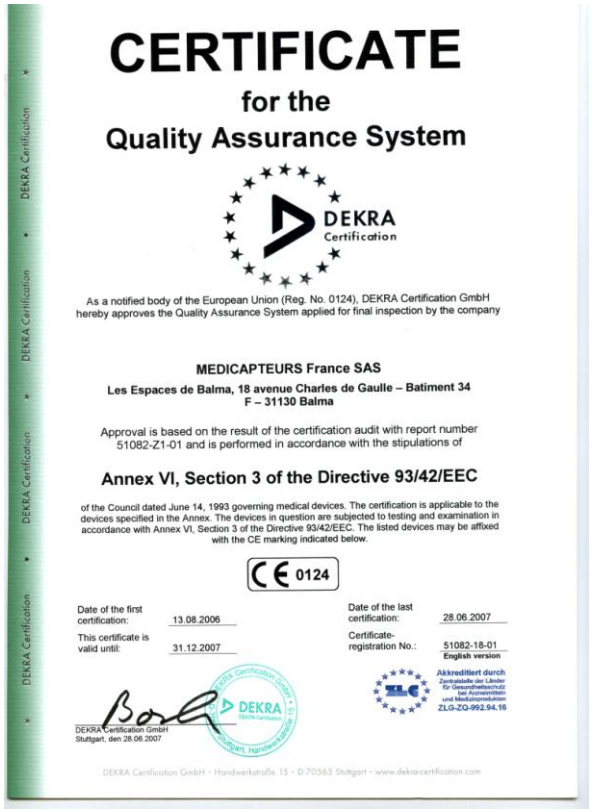
GESTION DE LA QUALITÉ
Certifié conforme
á la directive 93/42/CEE
relative aux dispositifs médicaux

GESTION DE LA QUALITÉ 93/42/CEE DEKRA CERTIFICATION

MEDICAPTEURS system is in accordance with these following norms :

- EN 60601-1-1 August 2001
- EN 60601-1-2 August 2005
- EN 60601-1-4 October 1999
- EN 60601-1-6 September 2007
- EN 62366 March 2008
- EN 62304 October 2006
- EN ISO 14971 November 2009

Medicapteurs is certified for its quality system.



CERTIFICATE
for the
Quality Assurance System

DEKRA Certification

As a notified body of the European Union (Reg. No. 0124), DEKRA Certification GmbH hereby approves the Quality Assurance System applied for final inspection by the company

MEDICAPTEURS France SAS
Les Espaces de Balma, 18 avenue Charles de Gaulle – Batiment 34
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Approval is based on the result of the certification audit with report number 51082-Z1-01 and is performed in accordance with the stipulations of

Annex VI, Section 3 of the Directive 93/42/EEC

of the Council dated June 14, 1993 governing medical devices. The certification is applicable to the devices specified in the Annex. The devices in question are subjected to testing and examination in accordance with Annex VI, Section 3 of the Directive 93/42/EEC. The listed devices may be affixed with the CE marking indicated below.

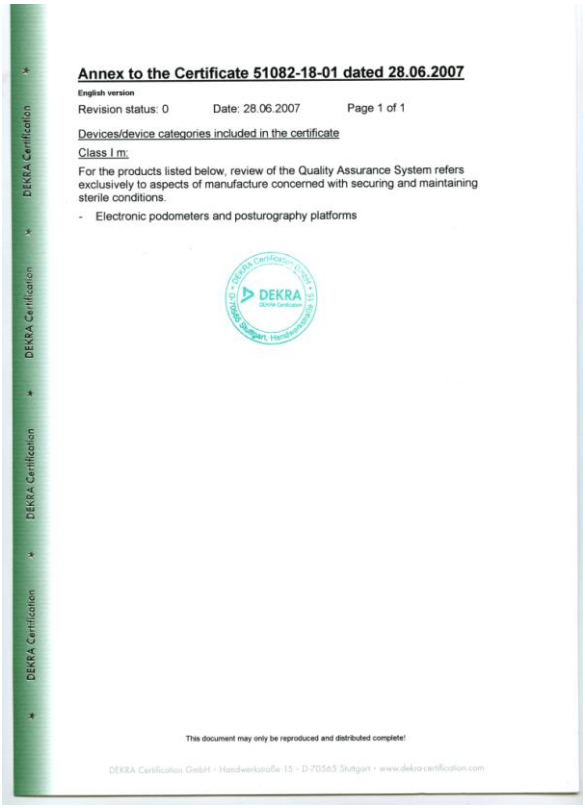
CE 0124

Date of the first certification: 13.08.2006
This certificate is valid until: 31.12.2007
Date of the last certification: 28.06.2007
Certificate-registration No.: 51082-18-01
English version

Akkreditiert durch Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-992.94.16

DEKRA Certification GmbH
Stuttgart, den 28.06.2007

DEKRA Certification GmbH · Handwerkstraße 15 · D-70565 Stuttgart · www.dekra-certification.com



Annex to the Certificate 51082-18-01 dated 28.06.2007

English version

Revision status: 0 Date: 28.06.2007 Page 1 of 1

Devices/device categories included in the certificate

Class I m:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Electronic podometers and posturography platforms

DEKRA Certification

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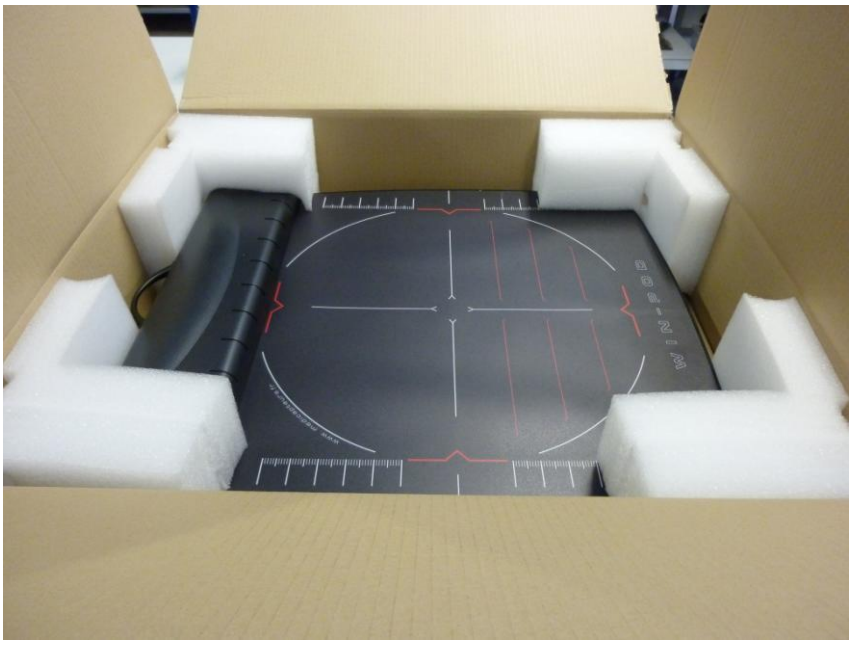
Package content

Check that your package contains :

- Platform
- Wire
- Installing and using manual
- Installing CDRom

LIMITATION ON WARRANTY

The platform is delivred in a customized packaging to protect the sensitive parts (electronic and sensors).



In case of after sale service, the warranty will not be applied if the product is not shipped back **in its original packaging**.
We recommend you to keep the original packaging even after the warranty period.
If needed, Medicapteurs will invoice a new packaging for you product shipment.

Available and spare parts

Suitcase
(Ref :ValiseWinPodFusyo)

Light suitcase
(Ref : Valiselight)

Positioner
(Ref :PositionneurWinpod)

2 meters wire
(Ref : CableWPod2)

WIN-POD presentation

Technical information

Size (Length/Width/Heigth)	600 x 530 x 45 mm
Thickness	4 mm
Active surface	400 x 400 mm
Weight	6,8 kg
Sensors type	Resistive
Sensor size	8 x 8 mm
Sensor number	2304 (48 x 48)
Min/max pressure range per sensor	from 0.4 to 100 N
Acceptable temperature (operation and storage)	from -40 to +85°C
Humidity	From 30 to 80 % HR
PC/platform connection type	USB
Power	via USB cable (5V, 400mA)
Power surge category	I
Acquisition frequency	Up to 200 images/sec

WIN-POD presentation

Medical purpose

This is a podometry platform which studies the foot pressure mapping and the orthostatic balance in static, dynamic or postural acquisition. It allows you to objectively assess biomechanical parameters of the foot for the pathology diagnostic process.
This platform can be used by many health specialties : Podiatry, Physical therapy, Sport Medicine, Rehabilitation, Orthopaedics, Rheumatology, Chiropractic…

Indications

Read the following instructions to install and use correctly the system.

Contraindications

Take care of patients with hard misbalance trouble while making acquisition. Some protocols needs to take care of the patient falling risk.

In order to be in accordance with the EN 60601-1 norm, current version, the platform doesn't have to be dismount.

Side effects

There is no side effect known.
The product development takes into consideration of skin allergy risk or electric shock hazard.

WIN-POD presentation

Hygiene/Cleaning

- After each patient, clean the platform upper surface with a product like «cleaning wipes» or any type of antiseptic wipes for medical devices. Do not use disinfectant spray.

- For a best hygiene quality, the patient must wear his socks, the measure modification is considered negligible.

Logos

CE : Medical Device in accordance with the ECC 93/42 Directive.

: DEKRA Certification Organism

0124 : Dekra Official Recording Number

: USB connection Device

: « B » type Device

: WEEE device (Medical Electric and Electronic Equipment).
Do not trash. Medicapteurs is in charge of its Waste recycling. The black rectangle means that the plaform was built after 8th August 2005.

: Incentive for user to read instructions.

WIN-POD presentation

READ IT BEFORE USING THE PLATFORM

The platform is a very sensitive and accurate tool. The sensor quality response depends on the **following instructions respect.**

Instructions

- The sensor life time depends on the indication respect. Take care of the platform when you move it.

- Please handle with caution the platform when you move, avoid shocks on the sensors. If you have to ship the platform, don't forget to protect the active area.

- **Always keep the same USB port on the PC** (do not change USB Plug-in).

- **The platform must be plugged exclusively into a normalized computer EN 60601-1 current version (particularly as it pertains to power connection)**. No peripheral device should be connected to the computer except if it is self powered (key board, mouse, USB key) or in compliance with regulations EN 60601-1, current version.

- Take care not to bend the connectors of the platform and to unplug the USB from the PC cable prior to any manipulation of the platform.

- **Save regularly your database.**

- In order to be in accordance with the EN 60601-1 norm, **the platform doesn't have to be dismount.**

- Do not expose the platform directly to the Sun (risk of burns).

- This product doesn't need any specific care about the EMC (electromagnetic compatibility). It is a EN 60601-1 current version certified product so it has been tested by an qualified official organism (Emitech).

- To make a good acquisition, the platform must be put on a hard, flat and not wet ground.

- If you stand on the platform with shoes, check if there is something dangerous for the platform (like stone, stud...). It's forbidden to walk with high heels.

- The patient must not step barefoot on the platform, provide socks if necessary to avoid potential allergies from foot/surface contact.

- The patient must not step on the hood of the platform, he must put his feet on the sensitive parts.

Software and driver installation

WARNING !!! IF YOU ALREADY HAVE A MEDICAPTEURS SOFTWARE ON YOUR COMPUTER, DON'T FORGETT TO SAVE THE DATABASE BEFORE INSTALLING THE NEW SOFTWARE.

Required configuration

You may contact us before hanging your computer.

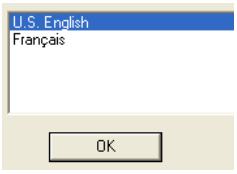
To install and use the software, you need a computer including these characteristics :

- **Type** : PC Quad Core minimum
- **Ram** : 4 Go minimum
- System : WINDOWS **XP**, **Vista, Seven** and **Eight**
- At least **2 USB ports dedicated**

Installation

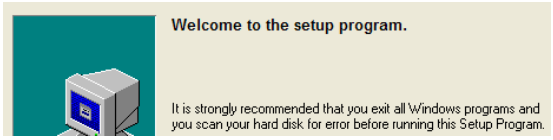
1. **Do not connect** your plateform.
2. Start your computer or close all applications if it's already on.
3. Put the software Cdrom on the reader.
4. Double-click on « Computer » icon then on your Cdrom reader.
5. Double-click on this icon

6. Choose the installation language and click on « OK ».



Software and driver installation

7. Windows displays this screen :



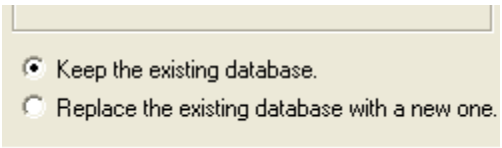
8. Then click 2 times on “Next”.
9. Choose the platform : select « Win-Pod ».

10. Choose the platform type : select « Win-Pod 2 (USB powered) ».

11. Choose your measuring system :

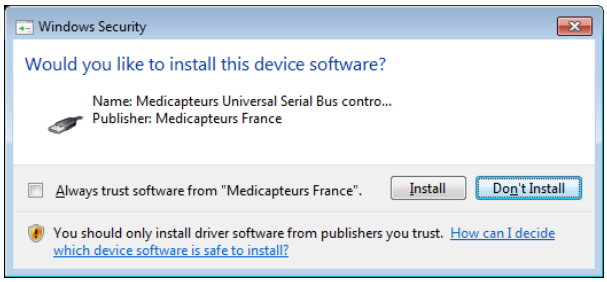
12. Choose your language :

13. If you already have a Medicapteurs’ product, **to keep your existing database**, choose :



Software and driver installation

14. During this installation, depending of your operating system, the following windows could appear, check « Always trust software from Medicapteurs France » and then click on « Install » :



15. During installation, a warning from your anti-virus could appear. Click on "Ok" to avoid to stop the installation.

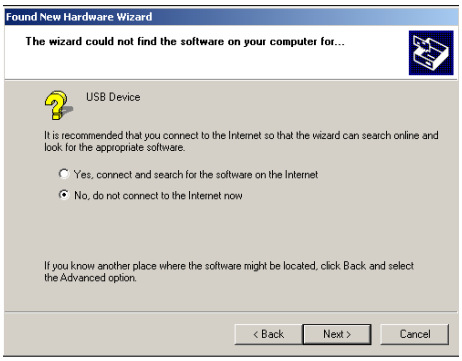
16. Then, click on « Finish » and on « OK » to restart your computer.

Connecting platform

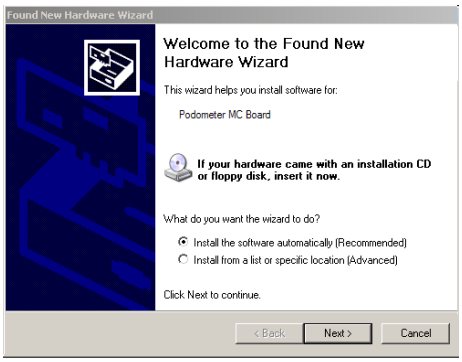
To make a good acquisition, the platform must be **imperatively** put on a hard and flat ground. The platform un-slide stands stabilize the platform on a slippery ground during the dynamic acquisition.

1. **Unplug all USB devices** (expect mouse and keyboard).
2. Take the wire then put it in the platform plug.
3. Screw the blue ring to lock it with the platform.
4. Link the USB plug with a PC USB port (a green light appears).
5. If you install on **Windows XP** follow the procedure described below, **otherwise skip to paragraph 6**.

    a. At the first connection of the platform to a USB port, Windows tries to connect to the internet, choose “No, do not connect to the internet now” and click on “Next” :

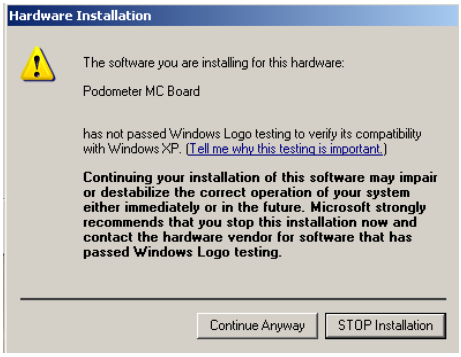


    b. Choose "Install the software automatically (Recommended)”, and click on “Next” :



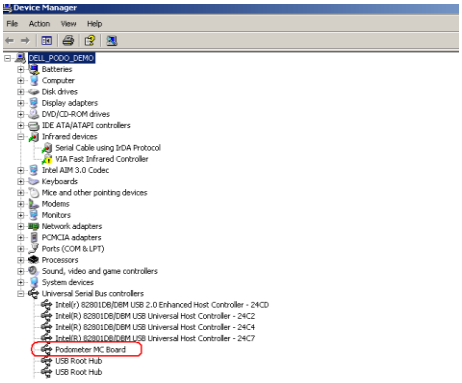
Connecting platform

c. Follow the process and click on “Continue Anyway” :



d. Click on “Finish” on the following window :

6. VERIFICATION : To check that the driver is correctly installed go to « Start / Control Panel / System / Hardware / Device Manager / USB controllers ».
The line « Podometer MC board » will appear if installation is correct.



Operation indicator

Thanks to the 3 leds, you can check the platform :

Red light Led flashes = Data transfert to the PC	Red light Led on = Plateform recognized by the PC (driver installed)	Green light Led on = Plateform powered by the PC

Medicapteurs database import

You can import MEDICAPTEURS database on the software :

To import your old MEDICAPTEURS database

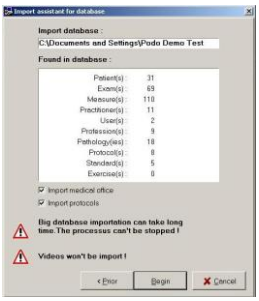
You can find the database on « data » folder on the software install folder.

In this sample, we copy the old PC database on a USB key to import it on the software

1. Open « DbManager » on the software install folder :

2. Click on « Database Import »

3. DB Manager displays tables to import
4. Click “Next”
5. DB Manager sum up the data to import, then click on “Begin” to proceed.



Using platform

Static acquisition

There is no gait reference. You only have to put the heels on the same line

The patient has to stand on the platform by the rear side.

To make a good acquisition, arms must be closed to the body and the sight looking at a target in front of him. Check that there is nothing on the patient's pockets.

You must see on the screen 2 grey lines appears on the rear of the heels. You need to move the patient's feet to make a single grey line.

To record the measure, please read the software User Manual.

Postural acquisition

Please follow the same procedure than « static acquisition ».
A 30° positioner is available in spare parts to help you for gait reference.

Posturology exams may be difficult for some patients with bad balance : stay closed to them.

Using platform

Dynamic acquisition

The patient must walk on the lateral way of the platform sighting the active surface (black square). Walk with an even natural stride. 2 steps need to be done before putting your lead foot on the platform then 2 steps for leaving.

Procedure to stop the platform

To stop the platform:

1. During acquisition, (just click on Cancel).

2. Exit the software (click on the X located on the upper right corner of the screen and then validate).

The system is on stanby (connected to the PC).

3. To cancel “standby” mode on the platform:

    a. Turn off computer.

    b. Disconnect the USB cable at the computer.