GIMA
PROFESSIONAL MEDICAL PRODUCTS

PODOSCOPIO GIMA A LED
GIMA LED PODOSCOPE
PODOSCOPE LED GIMA
PODOSCOPIO LED GIMA
PODOSCÓPIO LED GIMA
LED-PODOSKOP GIMA
GIMA PODOSCOPE LED
GIMAN LED-PODOSKOOPPI

Manuale d'uso - User Manual - Notice d'utilisation - Manual del usuario - Manual do utilizador - Gebrauchs- und instandhaltungsanleitung - Manual de utilizare - Ohjekirja

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.*
ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*
AVIS: *Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.*
ATENCIÓN: *Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.*
ATENÇÃO: *Os operadores devem ler e entender completamente este manual antes de usar o produto.*
ACHTUNG: *Diese Anleitung muss vor dem Einsatz des Produkts aufmerksam gelesen und vollständig verstanden werden.*
ATENTIE: *Operatorii trebuie sa citeasca și înțelegeți pe deplin acest manual mai întâi pentru a utiliza produsul.*
HUOMIO: *Käyttäjien on luettava ja ymmärrä tämä käsikirja ensin täysin käyttää tuotetta.*

REF **AP500GIMA (GIMA 27363)**

Tecniwork S.p.A.
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Bisenzio (FI) Italy
Made in Italy

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Chapter 1 GENERAL DESCRIPTION

1.1 General identification data

This instruction handbook is considered as an essential document of podoscope AP500GIMA (GIMA 27363). Therefore they must not be separated in case of cessation to third parties, in accordante with EC Directive 93/42/EC and following norms.
This handbook gives the operator all the relevant information to carry out the following operations correctly:
- INSTALLATION - USAGE - MAINTENANCE
Instructions for a correct installation are contained in the par. 2.2 CONDITIONS FOR THE INSTALLATION.

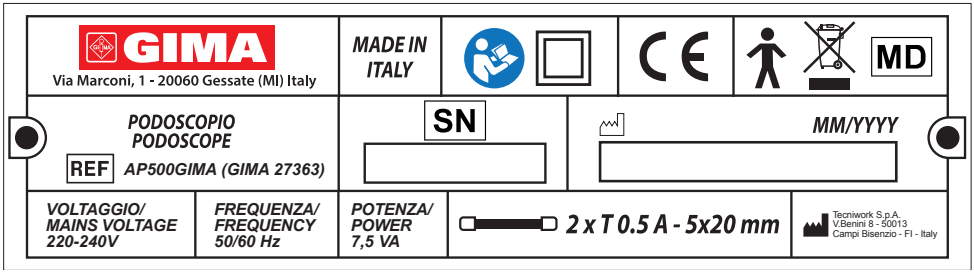
All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.

Company Name

Commercial Trademark: Gima
Typology: Podoscope
Model: AP500GIMA (GIMA 27363)
Manufacturer: Gima S.p.A. - Via Marconi, 1 20060 Gessate (MI) - Italy

Identification and labels, symbols explication

Warning: maximum load 135 kg (297 lbs)



On each device you will find a similar plate with the manufacturer's identification

1.2 Description and general characteristics

The particular system of light diffusion of the Podoscope AP500GIMA (GIMA 27363 enables you to study the patient's foot plant and to mark the parts with the heaviest pressure.

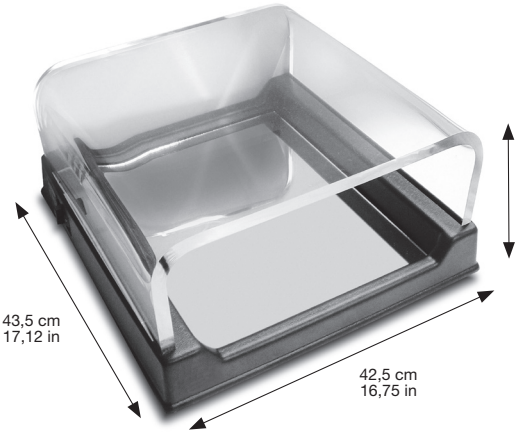
Its structure is very simple: the methacrylate structure is an excellent light conductor and it is also endowed with an inner light source: in this way you can discover variations of colour intensity on the foot plant, corresponding to higher or lower plant pressure.
The base is of ABS.

A separable net cable with plug, a jack, and a led strip are its electric components.

1.3 Technical features and voltage

Material	Transparent methacrylate

Tension	220-240 V single-phase
Frequency	50/60 Hz
Power	7,5 A
Illumination	Led Strip light
Wavelenght	520 nm
Risk Class EN 62471	Exempt
Nr. of included plugs	Nr. 1
2 Fuses:	5x20 mm: 2 x T 0,5 A – 250 V
Conditions of use	temperature: from 10°C up to 40°C
	umidity: from da 20% up to 85%
Stocking conditions:	temperature: from 0°C up to 60°C
	umidity: from da 10% up to 90%



Height	22 cm (8.67 in)
Total weight (with package)	Kg 9,0 (19.84 lb)
Maximum load	Kg 135 (297 lb)

1.4 Classification and reference norms

The Podoscope AP500GIMA (GIMA 27363) allows to evaluate the foot print, supplying secondary indirect information on the heel alignment and on the toes situation. It allows to evaluate the signs and the symptoms of a particular condition of the foot, in order to formulate a judgement on the health conditons and establish
a therapy or a chiropody treatment.
The device is designed and realized according to the law prescriptions
concerning electromedical equipment, and it's therefore indicated for medical purposes and used in clinics, consultation rooms and sports centres
by operators with knowledge of biomechanics, like doctors in sport medicine, orthopedic specialists and physiotherapists.

Reference harmonized norms:
- CEI EN 60601-1 "Safety of electromedical devices"
- CEI EN 60601-1-2 "Collateral harmonized norm for electromedical devices – Electromagnetic compatibility."

Classification according to safety norm EN 60601-1:
- Portable device

- Class II
- Type B
- Ordinary protection against humidity
- Do never use with inflammable anaesthetics
- Voltage: 220-240 V ~ 50/60 Hz.

The device highlights areas of the foot plant with heavest pressure thanks to different intensity of light. In order to visualize them the patient just needs to step on the podoscope barefoot. The particular features of this device grant adequate protection and isolation against direct or indirect electric shocksand against electric or mechanic surcharge.
The thermic power implied in this podoscope avoid dangerous overheating for materials and components.
Electric isolation and well-balanced distances between the surfaces avoid
the formation of electric arches. In addition to this, the podoscope has a solid mechanical structure and an excellent stability on the ground.
It has no sharp edges, therefore there exists no danger of mechanical nature both for operators and patients.
Each part of the inner circuits are assembled and fixed in such a solid way
so as to stand up to the often adverse transport conditions.

As to indirect shocks, the device is classified in Class II.
As to current leakage it can be classified in class B.

No essential performance is defined for this device.

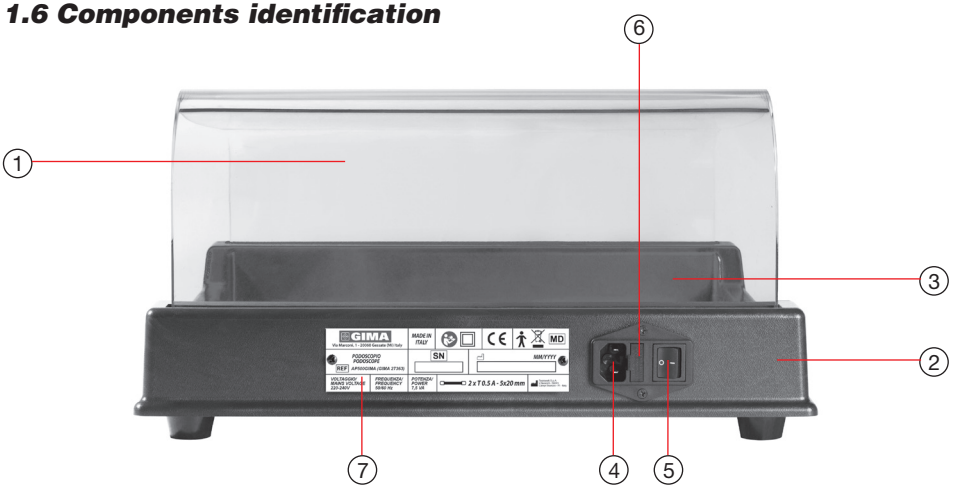
1.5 Electrical features of the podoscope

The conventional led power supply functions with single-phase current
(220-240 V - 50/60 Hz); the mark is ILC NanoLED.

The power cord - H05VV-F - 2 mt (6.56 ft) long, section 2 x 0.75 bears the mark IMQ, has a two-pole plug and it is connected to the podoscope through a connector.

The internal connectors of the power cord satisfy the norm CEI 20-20 (type H05V).

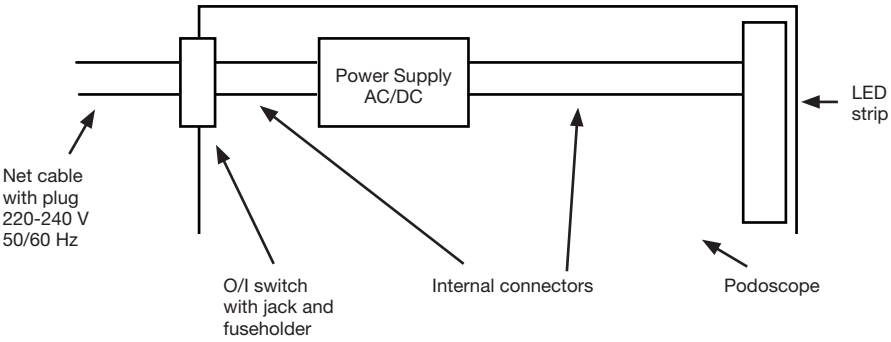
1.6 Components identification



1 - Transparent methacrylate surface

2 - Basement in ABS (acrylonitrile butadiene styrene with wiring)
3 - Mirror
4 - Power cord jack
5 - On/Off switch
6 - Fuse holder
7 - Identification plate

Electric schema



1.7 General safety warning

As far as safety is concerned, this podoscope has undergone all the necessary checks and inspections as foreseen.
In order to respect the safety prerequisites during the whole life of your device, we suggest that you always take the following precautions:

A. Always unplug the podoscope during maintenance operations.
B. Do not move the podoscope while using it.
C. Each time before the usage, check the functioning of the cable and of its electric parts.
D. Operators must not intervene or take any initiatives on the podoscope which are not foreseen in this handbook.

⚠ **Attention: do not charge the podoscope with loads over 135 kg (297 lb) in order to avoid any risk of breaking**

⚠ **Attention: no change of the device is allowed**

⚠ **Attention: not complying with warnings will relieve GIMA company from any kind of responsibility.**

Chapter 2 INSTALLATION

2.1 Trasport and stocking

Before shipping the podoscope AP500GIMA (GIMA 27363) is covered by a film and packed in a cardboard with protective panels inside.
The box contains the assembled podoscope and its cable (which must be obviously connected to the apparatus before using it); the caoutchouc
is not included.
In case of a longer storage, please store the whole package clean and dry.

2.2 Conditions for installation

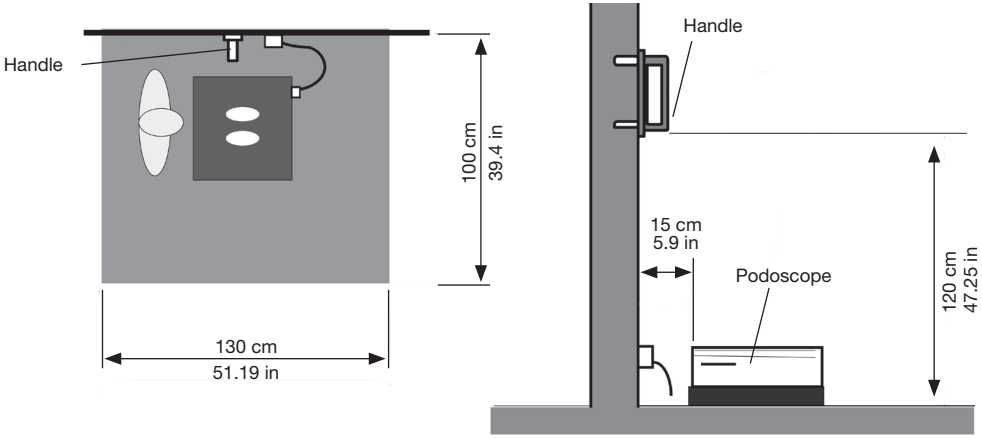
1. Unpack the podoscope completely.
2. Disposal of packing elements (plastic foams, polystyrene, polyethylene,

cardboard) must follow your local waste disposal guidelines.
3. Verify that the podoscope has not been damaged during transport. In case, please contact the manufacturer immediately.

IMPORTANT Please take notice of the fact that light stripes and/or microscopic luminescent dots on the transparent surface of the podoscope are due to the particular nature of its material and do not impair the equipment functionality.

Right positioning and safety installation of the podoscope

Position the podoscope so as to leave enough room around it to be able to safely operate and to connect and disconnect easily the device to the power supply network.
We suggest to attach a handle on the wall as indicated in the scheme below to make easier for patients to go on and down the podoscope.



Electromagnetic compatibility (EMC)

The podoscope needs special precautions concerning electromagnetic compatibility (EMC) and must be installed and operated according to the EMC information contained in this manual.

In order to avoid possible risks of electromagnetic interferences, do not use radio frequence portable or mobile devices near the podoscope.
Generally the podoscope should not be used near or together other equipements; in the case this would not be possible, it's necessary to observe its operativity to verify the normal functioning.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
The equipment **AP500GIMA (GIMA 27363)** is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment **AP500GIMA (GIMA 27363)** should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**

RF emissions CISPR 11	Group1	The equipment **AP500GIMA (GIMA 27363)** must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The AP500GIMA (GIMA 27363) is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose
Harmonic emissions IEC 61000-3-2	Compliant	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliant	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The equipment **AP500GIMA (GIMA 27363)** is intended for use in the electromagnetic environment specified below.
The customer or the user of the equipment **AP500GIMA (GIMA 27363)** should assure that it is used in such an environment.

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2 KV contact ±4 KV contact ±6 KV contact ±2 KV air ±4 KV air ±8 KV air	±2 KV contact ±4 KV contact ±6 KV contact ±2 KV air ±4 KV air ±8 KV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at less 30%
Electrical fast transient/burst IEC 61000-4-5	±2 KV for power supply lines	±2 KV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 KV differential mode ±2 KV common mode	±1 KV differential mode ±2 KV common mode	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	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for cycle 70% U_T (30% dip in U_T) for cycle <5% U_T (>95% dip in UT) for 5 s	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60%dip in U_T) for cycle 70% UT (30% dip in U_T) for cycle <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of AP500GIMA (GIMA 27363) requires continued operation during power mains interruptions, it is reccomended that the AP500GIMA (GIMA 27363) be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic field should beat levels characteristic of a typical location in a typical commercial or hospital environment.

2.3 Electric connection

Connect your podoscope verifying that the indications on the plate correspond to the local electric voltage, then plug it into the socket which must be supplied with a surcharge safety device.
The use of accessories, transducers and cables, except the ones sold by the producer as spare parts, can increase the emissions and decrease the EM (electromagnetic) device immunity.

Chapter 3 INSTRUCTIONS FOR USE

3.1 Use of the podoscope

Plug the podoscope in to light it up, then switch on (5) to position I.
Let the patient step on the transparent basis of the podoscope and make sure that the feet are right in the centre of it. Then proceed with a sight examination on the mirror.
If have not been supplied caoutchouc the examination can be performed only if the patient is barefoot, otherwise lay the caoutchouc on the transparent surface. This material is also useful to check the validity of arch support treatments.

Warning: don't let step on patients with injured foot skin

At the end of the examination, press (5) again to put it back to the 0 position and turn it off.

IMPORTANT: please help elderly patients step on the podoscope and remain steady

Chapter 4 MAINTENANCE

4.1 Ordinary maintenance

The ordinary maintenance described in this paragraph can be carried out directly by the operator.

1. Disinfect the surface of the podoscope after each use with disinfectants indicated for this material: **never use alcohol nor solvents for this purpose.**
2. Clean the podoscope at least once a week, always after having unplugged it. Use clean clothes, slightly moistened with water and detergent for glasses. **Never use alcohol nor solvents for this purpose**.
3. The frequency of the checks on internal wiring may vary according to external conditions (i.e. presence of dust) and repeated usage.
4. As a general rule, we recommend a sight inspection every six months or at least within one year after the purchase of the podoscope, to ascertain whether there is no wear and tear in the cable or in the electric connections.

If you have to replace one of the fuses, open the fuse holder placed in the position indicated in the picture on page 19.
Then get out the blown fuse with a suitable instrument and replace it with a T 0,5 A – 5x20 250V fuse.
If you have to replace the power cord, the new one must have the same characteristics and certification of the original one.
In the case of troubles or needs to replace spare parts, always contact the producer.

WARNING: all maintenance should be done only after disconnecting the device from the electrical mains.

LED replacement

In case of troubles with LED, please contact the Technical Assistance Service. Do not make direct operations, as Warranty shall become void.

WARNING: all the operations to replace led should be made only by the authorized technical assistance.

Index of symbols

	Caution: read instructions (warnings) carefully		Follow instructions for use
	Keep in a cool, dry place		Keep away from sunlight
	Manufacturer		Date of manufacture
REF	Product code	LOT	Lot number
CE	Medical Device compliant with Regulation (EU) 2017/	MD	Medical Device
	Device with applied part Type B		WEEE disposal
	Device of Class II		

4.2 Disposal

***Pursuant to legislative decree No. 49 of 14th March 2014**, "Implementation of Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)", the symbol of crossed-out wheeled bin shown on the equipment indicates that at the end of its life the product must be collected separately from other wastes.*
Separate collection of the present equipment at the end of its life is set up and operated by the manufacturer. The user who wishes to dispose of the present equipment shall therefore have to contact the manufacturer and use the system adopted by the latter to allow the end-of-life equipment to be separately collected. The proper separate collection of the discarded equipment for subsequent recycling, treatment and environmentally sound disposa helps to avoid potential negative consequences for the environment and human health and favours the re-use and/or recycling of the materials the equipment consists of. The abusive disposal of the product by its holder entails the enforcement of the administrative penalties envisaged by applicable legislation.

4.3 Technical support

If you need technical support, please contact GIMA.

5 Gima warranty terms

The Gima 12-month standard B2B warranty applies.