GIMA
PROFESSIONAL MEDICAL PRODUCTS

OXY-0 PEDIATRIC OXIMETER

Use and maintenance book

ATTENTION: Operators must read and understand this manual completely before using the product.

GIMA 35056

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IP22

M35056-EN-Rev.2.02.25

CMS2.782.507(CE)ESS/1.3 1.4.01.51.265 2025.01

User Notice

Dear users, thank you very much for purchasing the Pulse Oximeter (hereinafter referred to as device).

This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

It is a medical device, which can be used repeatedly.

The Manual describes, in accordance with the device's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and device. Refer to the respective chapters for details.

Please read the User Manual carefully before using this device. The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause measuring abnormality, device damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and device damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.

Our company has the final interpretation to this manual. The content of this manual is subject to change without prior notice.

Warnings

Remind that it may cause serious consequences to tester, user or environment.

- Explosive hazard—DO NOT use the device in environment with inflammable gas such as anesthetic.
- DO NOT use the device while examining by MRI or CT, as the induced current may cause burn.
- Do not take the information displayed on the device as the sole basis for clinical diagnosis. The device is only used as an auxiliary means in diagnosis. And it must be used in conjunction with doctor's advice, clinical manifestations and symptoms.
- The maintenance to the device,can only be performed by qualified service personnel specified by manufacturer. Users are not permitted to maintain or refit the device by themselves.Unauthorized modification of the device would result unacceptable risk.
- Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation disturbance users. It is not recommended that the sensor is used on the same finger for more than 2 hours.
- For some special users who need a more careful inspection on the test site, please don't place the device on the edema or tender tissue.
- Please do not stare at the red and infrared light emitter (the infrared light is invisible) after turning on the device, including the maintenance staff, as it may be harmful to the eyes.
- Each part of the device is firmly fixed,if accidental falling leads to the small parts such as a button to fall off,avoid swallowing of these parts,it may cause suffocation.
- The device contains silicone, PVC, TPU, TPE and ABS materials, whose biocompatibility has been tested in accordance with the requirements in ISO 10993-1, and it has passed the recommended biocompatibility test. The person who is allergic to silicone, PVC, TPU, TPE or ABS can not use this device.
- Do NOT strand the lanyard to avoid device drop and damage. The lanyard is made of insensitive material. Please do not use it if any person is allergic to lanyard. Do not wrap the lanyard around neck to avoid an accident.
- The disposal of scrap device, its accessories and packaging should follow the local laws and regulations, to avoid polluting to the local environment. And the packaging materials must be placed in the region where the children are out of reaching.
- The device can not be used with the equipment not specified in the Manual. Only the accessories appointed or recommended by the manufacturer can be used, otherwise it may cause injury to the tester and operator or damage to the device.
- Check the device before use to make sure that there is no visible damage that may affect user's safety and device performance. When there is obvious damage, please replace the damaged parts before use.
- Functional testers can not be used to assess the accuracy of the SpO_2 probe and Pulse Oximeter.
- Some functional testers or patient simulators can be used to verify whether the device works normally, for example, INDEX-2LFE Simulator (software version: 3.00), please refer to the Manual for the detailed operation steps.
- Some functional testers or patient simulators can measure the accuracy of the device copied calibration curve, but they can not be used to evaluate the device accuracy.
- When using the device, please keep it away from the equipment which can generate strong electric field or strong magnetic field. Using the device in an inappropriate environment may cause interference to the surrounding radio equipment or affect its working.
- When storing the device, keep it away from children, pets and insects to avoid affecting its performance.
- Do not place the device in places exposed to direct sunlight, high temperature, humidity, dust, cotton wool or easy to splash water, to avoid affecting its performance.
- The measured accuracy will be affected by the interference of electrosurgical equipment.
- When several products are used on the same patient simultaneously, danger may occur which is arisen from the overlap of leakage current.
- CO poisoning will appear excessive estimation, so it is not recommended to use the device.
- This device is not intended for treatment.
- The intended operator of the device may be a patient
- Avoid maintaining the device during using.
- Users should read the product manual carefully before use and operate according to the requirements.

1 Overview

The oxygen saturation is the percentage of HbO_2 in the total Hb in the blood, so-called the O_2 concentration in the blood, it is an important physiological parameter for the respiratory and circulatory system. A number of diseases related to respiratory system may cause the decrease of SpO_2 in the blood, furthermore, some other causes such as the malfunction of human body's self-adjustment, damages during surgery, and the injuries caused by some medical checkup would also lead to the difficulty of oxygen supply in human body, and the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc. Serious symptoms might bring danger to human's life. Therefore, prompt information of patients' SpO_2 is of great help for the doctor to discover the potential danger, and is of great importance in the clinical medical field.

Insert the finger when measuring, the device will directly record the SpO_2 value measured, it has higher accuracy and repeatability.

1.1 Features

A. Easy to use.
B. Small in volume, light in weight, convenient to carry.
C. Low power consumption.

1.2 **Intended purpose**

The Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through finger. The product is suitable for being used in family, hospital, oxygen bar, community healthcare, physical care in sports (It can be used before or after doing sports, and it is not recommended to use the device during the process of having sport) and etc.

1.3 Environment requirements

Storage Environment
a) Temperature :-40 ℃ ~ +60 ℃
b) Relative humidity :≤95%
c) Atmospheric pressure :500 hPa ~ 1060 hPa

Operating Environment
a) Temperature:+10 ℃ ~ +40 ℃
b) Relative Humidity :≤75%
c) Atmospheric pressure:700 hPa ~ 1060 hPa

1.4 Precautions

1.4.1 Attention

Point out conditions or practices that may cause damage to the device or other properties.

- Before using the device, make sure that it locates in normal working state and operating environment.
- In order to get a more accurate measurement, it should be used in a quiet and comfortable environment.
- When the device is carried from cold or hot environment to warm or humid environment, please do not use it immediately, wait four hours at least is recommended.
- If the device is splashed or coagulated by water, please stop operating.
- DO NOT operate the device with sharp things.
- High temperature, high pressure, gas sterilizing or immersion disinfection for the device is not permitted. Refer to User Manual in the relative chapter (6.1) for cleaning and disinfection.Please take out the internal battery before cleaning and disinfection.
- The product is suitable for people with finger diameters greater than 5mm.
- The device may not be suitable for all patients, if you can't get a satisfactory result, please stop using it.
- Data averaging and signal processing have a delay in the upgrade of SpO_2 data values. When the data update period is less than 30 seconds, the time for obtaining dynamic average values will increase, which is arisen from signal degradation, low perfusion or other interference, it depends on the PR value.
- The device has 3-year service life, date of manufacture sees the label.
- The device does not provide over-limit alarm function for SpO_2 and PR, so it is inapplicable for using in the place where need such function.
- The device hasn't low-voltage alarm function, it only shows the low-voltage, please change the battery when the battery voltage is used up.
- The maximum temperature at the SpO_2 probe -tissue interface should be less than 41℃ which is measured by the temperature tester.
- During measuring, when abnormal conditions appear on the screen, please pull out your finger and reinsert it to measure again.
- If some unknown error appears during measuring, remove the battery to terminate operating.
- Do not contort or drag the wire of the device.
- The plethysmographic waveform is not normalized, as a signal inadequacy indicator, when it is not smooth and stable, the accuracy of the measured value may degrade. When it tends to be smooth and stable, the measured value read is the optimal and the waveform at this time is also the most standard.
- If the device or component is intended for single-use, then the repeated use of these parts will pose risks on the parameters and technical parameters of the equipment known to the manufacturer.
- If necessary, our company can provide some information (such as circuit diagrams, component lists, illustrations, etc.), so that the qualified technical personnel of the user can repair the device components designated by our company.
- The measured results will be influenced by the external colouring agent (such as nail polish, colouring agent or color skin care products, etc.), so don't use them on the test site.
- As to the fingers which are too cold or too thin or whose fingernail is too long, it may affect the measured results, so please insert the thicker finger such as thumb or middle finger deeply enough into the probe when measuring.
- The finger should be placed correctly (see Attached figure 6), as improper installation or improper contact position for sensor will influence the measurement.
- The light between the photoelectric receiving tube and the light-emitting tube of the device must pass through the subject's arteriole. Make sure the optical path is free from any optical obstacles like rubberized fabric, to avoid inaccurate results.
- Excessive ambient light may affect the measured results, such as surgical light (especially xenon light sources), bilirubin lamp, fluorescent lamp, infrared heater and direct sunlight, etc. In order to prevent interference from ambient light, make sure to place the sensor properly and cover the sensor with opaque material.
- Frequent movement (active or passive) of the subject or severe activity can affect the measured accuracy.
- The SpO_2 probe should not be placed on a limb with the blood pressure cuff, arterial ductus or intraluminal tube.
- The measured value may be inaccurate during defibrillation and in a short period after defibrillation, as it has not defibrillation function.
- The device has been calibrated before leaving factory.
- The device is calibrated to display functional oxygen saturation.
- The equipment connected with the Oximeter interface should comply with the requirements of IEC 60601-1.

1.4.2 Clinical restriction

A. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.

B. The measurement will be influenced by intravascular staining agents (such as indocyanine green or methylene blue), skin pigmentation.

C. The measured value may be normal seemingly for the tester who has anemia or dysfunctional hemoglobin(such as carboxyhaemoglobin (COHb), methaemoglobin (MetHb) and sulfhaemoglobin (SuHb)), but the tester may appear hypoxia, it is recommended to perform further assessment according the clinical situations and symptoms.

D. Pulse oxygen only has a reference meaning for anemia and toxic hypoxia, as some severe anemia users still show better pulse oxygen measured valued.

E. Contraindication:

a. The person who is allergic to silicone, PVC, TPU TPE or ABS.
b. The damaged skin tissue.
c. During cardiopulmonary resuscitation.
d. When the patient is hypovolemic.
e. For assessing the adequacy of ventilatory support.
f. For detecting worsening lung function in patients on a high concentration of oxygen.

1.5 Clinical indications

The Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through finger.

2 Principle

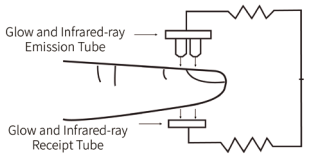

Figure 1 Operating principle

An experience formula of data processing is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in red light & near-infrared light zones. On the basis of the principle of Photoelectric Oxyhemoglobin Inspection Technology and Photoplethysmography technology, it uses two light beams of different wavelengths to irradiate the human fingertip to obtain the measurement information from the photosensitive element, after processed by the electronic circuits and microprocessor, displays the measured results on the screen.

3 Functions

A. SpO_2 value display
B. PR value and bar graph display
C. Pulse waveform display
D.The display mode can be changed
E.Adjustable screen brightness
F. Automatic standby function
G. Low-battery indication: low-battery indication appears when the battery voltage is too low to work
H. Display direction can be changed automatically.

4 Installation

4.1 Interface introduction

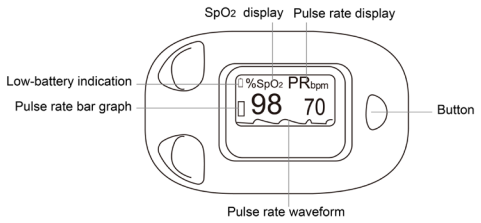

Figure 2 Measurement interface

4.2 Battery

Step 1. Refer to Figure 3. and insert the two AAA size batteries properly in the right direction.
Step 2. Replace the cover, turn the screw.

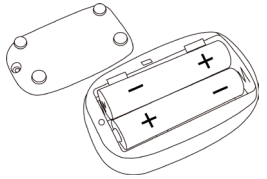

Figure 3 Batteries installation

⚠ **Please take care when you insert the batteries for the improper insertion may damage the device.**

4.3 Mounting the Hanging Rope

Step 1. Put the end of the rope through the hole.
Step 2. Put another end of the rope through the first one and then tighten it.

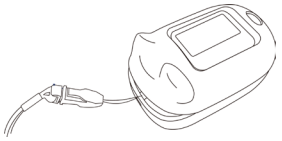

Figure 4 Mounting the hanging rope

4.4 Structure, accessories,software

A. Structure: main unit.

B. Accessories: one User Manual, one hanging rope(optional), one cartoon stickers,two batteries(optional).

⚠ **Please check the device and accessories according to the list to avoid that the device can not work normally.**

C. Software description

Release version: V2

5 Operating

5.1 Measurement

1) Insert the two batteries properly to the direction, and then replace the cover.
2) Open the clip as shown in Figure 5.

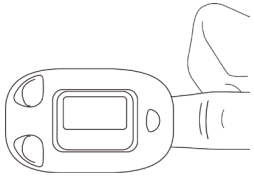

Figure 5 Put finger in position

3) Let the user's finger put into the rubber cushions of the clip (make sure the finger is in the right position),and then clip the finger.
4) Press the button once on front panel.
5) Do not shake the finger and keep the user at ease during the process. Meanwhile, human body is not recommended in movement status.
6) Get the information directly from screen display.
7) The device could change display direction according to the handing direction.
8) The button has two functions.When the device is in standby mode, pressing the button can exit it; When the device is in operation status, pressing the button long can change brightness of the screen.

⚠ **Fingernails and the luminescent tube should be on the same side.**

6 Maintain, Transport and Storage

6.1 Cleaning and disinfection

Please take out the internal battery before cleaning, do not immerse it into liquid.

Use 75% alcohol to wipe the device enclosure and the nail pad,nature dry or clean it with clean and soft cloth. Do not spray any liquid on the device directly, and avoid liquid penetrating into the device.

6.2 Maintenance

A. Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance. It is recommended that the device should be inspected weekly at least. When there is obvious damage, stop using it.

B. Please clean and disinfect the device before/after using it according to the User Manual (6.1).

C. Please replace the batteries in time when low-battery appears.

D. Please take out the batteries if the device is not used for a long time.

E. The device need not to be calibrated during maintenance.

6.3 Transport and Storage

A. The packed device can be transported by ordinary conveyance or according to transport contract. During transportation, avoid strong shock, vibration and splashing with rain or snow, and it can not be transported mixed with toxic, harmful, corrosive material.

B. The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -40℃~+60°C; Relative humidity: ≤95%.

7 Troubleshooting

Trouble	Possible Reason	Solution
The values can not be displayed normally or stably.	The finger is shaking or the user is moving. 2) The device is not used in environment required by the manual. 3) The device works abnormally.	again. 2) Let the user keep calm. 3) Please use the device in normal environment. 4) Please contact the after-sales.
The device can not be turned on	1) The battery is drained away or almost drained away. 2) The battery is installed incorrectly. 3) The device's malfunction.	1) PPlease change batteries. 2) Please Install the battery again. 3) Please contact the local service center.
The display disappears suddenly.	1) Low battery. 2) The device works abnormally.	1) Please change the battery. 2) Please contact the after-sales.

8 Symbols

Symbol	Meaning	Symbol	Meaning
	Follow instructions for use	PRbpm	Pulse rate (bpm)
	Type BF applied part	%SpO_2	Pulse oxygen saturation (%)
	Manufacturer		Full-voltage
SN	Serial number		Expiration date
	WEEE disposal		1. No finger inserted 2. Signal inadequacy indicator
+	Battery anode	−	Battery cathode
IP22	Covering Protection rate		Alarm inhibit
	Temperature limit		Humidity limit
	Atmospheric pressure limit		This way up
	Fragile, handle with care		Keep in a cool, dry place
	Low battery		Open the sound prompt
	Power button		Open the PR sound
	Recyclable		Manufacture Date
Finger Out Out	The finger is not inserted.	EC REP	Authorized representative in the European community
P/N	Material code	LOT	Lot number
CE	Medical Device compliant with Directive 93/42/EEC		Keep away from sunlight
	Caution: read instructions (warnings) carefully		Imported by
REF	Product code	UK REP	Authorized Representative in the UK

Note：Your device may not contain all the following symbols.

9 Specification

SpO_2 [see note 1]	
Display range	0% ~ 99%
Measured range	0% ~ 100%
Accuracy [see note 2]	70%~100%: ±2%; 0%~69%: unspecified.
Resolution	1%
PR	
Display range	30 bpm ~ 250 bpm
Measured range	30 bpm ~ 250 bpm
Accuracy[see note 3]	±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm.
Resolution	1 bpm
Accuracy under low perfusion [see note 4]	Low perfusion 0.4%: SpO_2: ±4%; PR:±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm.
Light interference	Under normal and ambient light conditions, the SpO_2 deviation ≤ 1%
Pulse intensity	Continuous bar graph display, the higher display indicates the stronger pulse.
Optical sensor [see note 5]	
Red light	Wavelength: about 660 nm, optical output power: < 6.65 mW
Infrared light	Wavelength: about 905 nm, optical output power: < 6.75 mW
Safety class	Internally powered equipment, type BF applied part
International Protection	IP22
Working voltage	DC 2.6 V - 3.6 V
Working current	≤ 30 mA
Power supply	1.5 V (AAA size) alkaline batteries × 2
Operation time	The device can continuously work for 20 hours when it was powered by two new batteries within the warranty period.
Dimension and Weight	
Dimension	59(L) × 37(W) × 35(H) mm
Weight	About 50 g (with the batteries)

Note 1: the claims of SpO_2 accuracy shall be supported by clinical study measurements taken over the full range. By artificial inducing, get the stable oxygen level to the range of 70 % to 100 % SpO_2, compare the SpO_2 values collected by the secondary standard pulse oximeter equipment and the tested equipment at the same time, to form paired data, which are used for the accuracy analysis.

There are 12 healthy volunteers (male: 6. female: 6; age: 18~50; skin color: black: 2, light: 8, white: 2) data in the clinical report.

Note 2: because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ±Arms of the value measured by a CO-OXIMETER.

Note 3: Patient simulator has been used to verify the pulse rate accuracy, it is stated as the root-mean-square difference between the PR measurement value and the value set by simulator.

Note 4: percentage modulation of infrared signal as the indication of pulsating signal strength, patient simulator has been used to verify its accuracy under conditions of low perfusion. SpO_2 and PR values are different due to low signal conditions, compare them with the known SpO_2 and PR values of input signal.

Note 5: optical sensors as the light-emitting components, will affect other medical devices applied the wavelength range. The information may be useful for the clinicians who carry out the optical treatment.For example, photodynamic therapy operated by clinician.

EMC

This equipment is suitable for professional healthcare facility environments and home healthcare environments

⚠ **Warning**

- Don't near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the this equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ **Note:**

- this equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- The basic performance:. SpO_2 measured range: 70% ~ 100%, absolute error: ±2%; PR measured range: 30 bpm ~ 250 bpm, accuracy:±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm.
- When the device is disturbed, the data measured may fluctuate, please measure repeatedly or in another environment to ensure its accuracy.
- Other devices may affect this device even though they meet the requirements of CISPR.

Table 1:

Guidance and Declaration - Electromagnetic Emissions	
Emission test	**Compliance**
Radiated RF EMISSIONS CISPR 11	Group 1
Radiated RF EMISSIONS CISPR 11	Class B
Harmonic distortion IEC 61000-3-2	Not applicable
Voltage fluctuations and flicker IEC 61000-3-3	Not applicable

Table 2:

Guidance and Declaration - Electromagnetic Immunity		
Immunity test	IEC60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15 kV air	±8kV contact ±15kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable
Surge IEC 61000-4-5:	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not Applicable
Voltage dips and Voltage interruptions IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°,45°,90°,135°,180°,225°,270°and 315° 0 % U_T; 1 cycle and 70 % U_T ; 25/30 cycles ; Single phase:at 0°. 0 % U_T ; 250/300 cycle	Not Applicable
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	3 V 0,15MHz - 80 MHz 6 V in ISM and amateur radio bands between 0,15MHz to 80 MHz 80%AM at 1kHz	Not Applicable
Radiated RF IEC61000-4-3	10V/m 80 MHz-2,7GHz 80%AM at 1kHz	10V/m 80 MHz-2,7GHz 80%AM at 1kHz
NOTE U_T is the a.c.mains voltage prior to application of the test level		

Table 3:

Guidance and manufacturer's declaration - electromagnetic Immunity						
	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC60601-1-2 Test level (V/m)	Compliance level (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380–390	TETRA 400	Pulse modulation b) 18 Hz	27	27
	450	430 – 470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	28	28
	710 745 780	704 –787	LTE Band 13,17	Pulse modulation b) 217 Hz	9	9
	810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	28	28
	1720 1845 1970	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation b) 217 Hz	28	28
	2450	2400 –2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	28	28
	5240 5500 5785	5100 –5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	9	9

Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment*

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies