

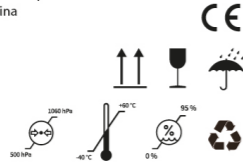
OXY-50 VET PULSE OXIMETER with software

REF CMS60D-VET (GIMA 80800)

Contact Medical System Co., Ltd
Address: No 112 Qinhuang West Street, Economic&Technical Development Zone, Qinhuangdao, Hebei Province, People's Republic of China
Made in China

EC REP Prolinx GmbH, Brehmstr. 56,
40239 Dusseldorf Germany

Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com



User Notice

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

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 the 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 animal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, animal 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 test animal, 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 barrier animal. It is recommended that the sensor should not be applied to the same part for over 2 hours.
- ⚠ For the special animal, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and 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. Animals allergic to silica gel, PVC, TPU, TPE or ABS cannot use this device.
- ⚠ 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 test animal and operator or damage to the device.
- ⚠ The SpO₂ probe accompanied is only suitable for using with the device. The device can only use the SpO₂ probe described in the Manual, so the operator has the responsibility to check the compatibility between the device and the SpO₂ probe before using, incompatible accessories may cause device performance degradation, device damage or animal injury.
- ⚠ Do not reprocess the accompanying SpO₂ probe.
- ⚠ Check the device before use to make sure that there is no visible damage that may affect animal's safety and device performance. When there is obvious damage, please replace the damaged parts before use.
- ⚠ When the message "Sensor Off" or "Sensor Fault" appears on the screen, it indicates that the SpO₂ probe is disconnected or line fault occurs. Check the connection of the SpO₂ probe and whether there is damage for the probe, if necessary, please replace the probe to avoid risks. The probe fault will not result in a safety hazard.
- ⚠ Functional testers can not be used to assess the accuracy of the SpO₂ probe and Veterinary 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 animal 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 an animal.
- ⚠ Avoid maintaining the device during using.
- ⚠ Users should read the product manual carefully before use and operate according to the requirements.

1 Overview

The pulse oxygen saturation is the percentage of HbO₂ in the total Hb in the blood, so-called the O₂ concentration in the blood. It is an important bio-parameter for the respiration. For the purpose of measuring the SpO₂ more easily and accurately, our company developed the Veterinary Pulse Oximeter. At the same time, the device can measure the pulse rate simultaneously. The Veterinary Pulse Oximeter features in small volume, low power consumption, convenient operation and being portable.

It is only necessary for animal to put tongue or ear into a probe for diagnosis, and a display screen will directly show the measured value of pulse oxygen saturation with the high veracity and repetition.

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 Veterinary Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through animal's tongue or ear so on. The product is suitable for being used in family. (It is recommended to use the device when the animal is still.)

1.3 Environment requirements

Storage Environment

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

Operating Environment

- a) Temperature: +10 °C ~ +40 °C
- 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 device is suitable for animal.
- ⚠ The device may not be suitable for all animals, if you can't get a satisfactory result, please stop using it.
- ⚠ Data averaging and signal processing have a delay in the upgrade of SpO₂ 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 expected service life of the attached parts or accessories of the equipment is two year.
- ⚠ If the shelf life is less than the expected service life, the shelf life of the attached parts or accessories of the equipment is two year.
- ⚠ The device does not provide over-limit alarm function for SpO₂ and PR, so it is inapplicable for using in the place where need such function.
- ⚠ This device has the function of prompting, users can check on this function according to chapter 6.1 as a reference.
- ⚠ The device has the function of limits prompting, when the measured data is beyond the highest or lowest limit, the device would start prompting automatically on the premise of the prompting function is on.
- ⚠ The device has the function of prompting, this function can either be paused, or closed for good. This function could be turned on through menu operation if you need. Please check the chapter 6.1 as a reference.
- ⚠ 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 SpO₂ probe -tissue interface should be less than 41°C which is measured by the temperature tester.
- ⚠ During measuring, when abnormal conditions appear on the screen, please pull out the measured part 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 necessary, please visit our official website to get the information about SpO₂ probe that can be used with this device.
- ⚠ 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 hair which is too long or too thick may affect the measure value. Please insert hair thin part enough into the probe, or eliminate the hair of the part which will be measured.
- ⚠ The measured part 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 animal'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 animal or severe activity can affect the measured accuracy.
- ⚠ The SpO₂ 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 animal is required. For a animal with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO₂ 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 test animal who has anemia or dysfunctional hemoglobin (such as carboxyhaemoglobin (COHb), methaemoglobin (MetHb) and sulphaemoglobin (SuHb)), but the test animal 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 animal still show better pulse oxygen measured valued.
- E. Contraindication:
 - a. The animal who is allergic to silicone, PVC, TPU TPE or ABS.
 - b. The damaged skin tissue.
 - c. During cardiopulmonary resuscitation.
 - d. When the animal is hypovolemic.
 - e. For assessing the adequacy of ventilatory support.
 - f. For detecting worsening lung function in animals on a high concentration of oxygen.

1.5 Clinical indications

The Veterinary Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through tongue or ear.

2 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 (HbO₂) 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 animal's tongue or ear to obtain the measurement information from the photosensitive element, after processed by the electronic circuits and microprocessor, displays the measured results on the screen.

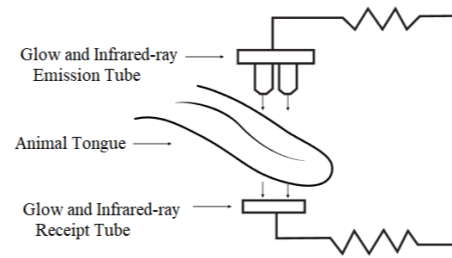


Figure 1

3 Functions

- A. SpO₂ value display
- B. Pulse rate value display, bar graph display
- C. Pulse waveform display

- D. Low-voltage indication: low-voltage indicator appears before working abnormally which is due to low-voltage
- E. Screen brightness can be changed
- F. Pulse sound indication
- G. With prompt function
- H. With SpO₂ value and pulse rate value record function, the stored data can be uploaded to computer
- I. It can be connected with an external oximeter probe
- J. Real-time data can be transmitted to computer
- K. Review function
- L. Clock function

4 Installation

4.1. View of the front panel

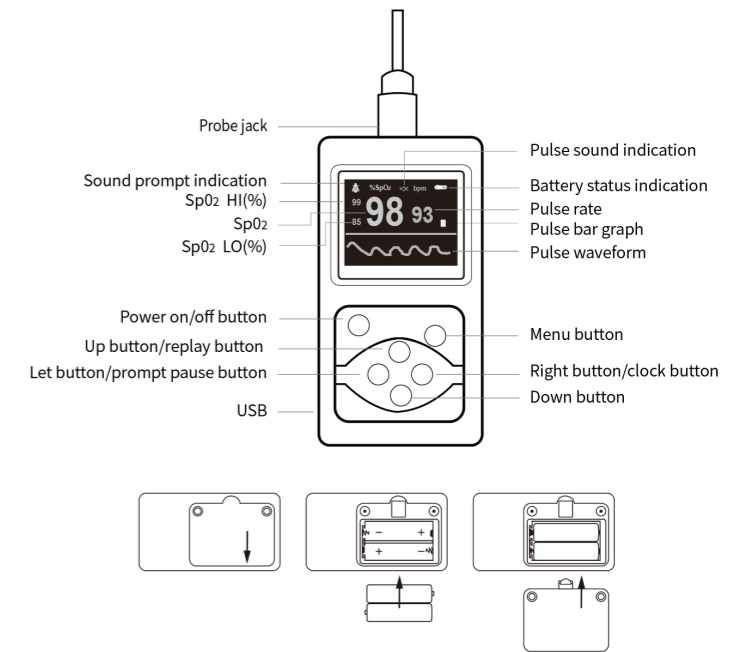


Figure 2. Front View

4.2. Battery installation

Figure 3. Batteries Installation

- A. Refer to Figure 3. Use a screwdriver to unscrew the two screws from the battery compartment on the back of the product and open the back cover of the battery compartment.
- B. Insert the two AA size batteries properly in the right direction.
- C. Replace the cover, screw on the screw.

- ⚠ Please take care when you insert the batteries, for the improper insertion may damage the device.
- ⚠ Please replace two new batteries of the same kind at the same time.

4.3. Probe installation

Inserting the SpO₂ probe of the Veterinary Pulse Oximeter in the upper jack (see Figure 4). (The probe is limited to be produced by our company; never replace it with the similar one by other manufacturers).

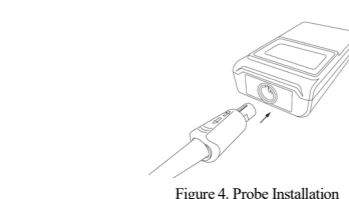


Figure 4. Probe Installation

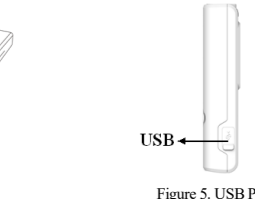


Figure 5. USB Port

- ⚠ when inserting the probe, make the protruding part of the probe plug correspond to the groove of the probe socket. Pull out the probe directly and don't rotate the probe.

4.4. USB port

It is used to connect a personal computer to export the trend data (see Figure 5).

4.5. Structure, accessories and software description

- A. Structure: main unit, probe, USB cable.
- B. Accessories: one animal-oximeter probe, two AA size batteries (optional), one USB cable, one CD disk (including PC software, optional), one User Manual.

- ⚠ 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. Application method

- A. Put the animal tongue enough into the animal nip of probe. Refer to Figure 6.

