551B Veterinary SpO₂ Sensor Instructions for Use

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This manual provides the instructions necessary to operate the product in accordance with its function and intended use. Observance of this manual is a prerequisite for proper performance and correct operation, and ensures animal and operator safety.

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- This product is operated under strict observance of this manual.

 This product is not damaged by human factors. Human factors refer to unintentional falling, intentional

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Product Introduction

Intended Use

The 551B veterinary SpO₂ sensor includes sensor pads, cables, connector and two clips with different size. The reusable 551B veterinary SpO₂ sensor is applicable to canine and feline animals for spot check or continuous noninvasive measurement of arterial oxygen saturation and pulse rate.

The 551B veterinary SpO₂ sensor must be used in connection with the monitoring device (including accessories) specified by our company that supports the veterinary SpO₂ measurement function. The user shall be responsible for ensuring the compatibility between this sensor and the monitoring device (including accessories) by either referring to the instructions for using this sensor or contacting us before use. These sensors must be used by trained clinical professionals. Otherwise, it may damage the accessory or equipment, or bring harm to the animal.

Select the corresponding SpO2 extension cable based on the type of SpO2 connector.

Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. Change the application site every four hours. For animals with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.

Warnings

- Check the sensor and the cable before using. Do not use them for SpO2 monitoring in case of damage, block, deterioration or visible contamination.
- Change the clip in case of cracking, breakage or loss of spring tension.

 For disposal of accessories, follow local regulations or your hospital's policy regarding disposal
- of such accessories. Do not dispose randomly.

 To reduce the impact on the measurement of electrical surgical equipment, do not place the sensor cable near to the power lines of surgical equipment.
- The SpO₂ sensor must be used in connection with the specified equipment only. The user shall be responsible for ensuring the compatibility between this sensor, the extension cable and other
- equipment by either referring to the instructions for using this sensor or contacting us before use. Carefully route cables to reduce the possibility of animal entanglement or strangulation.
- Do not bend the cable excessively for a prolonged time.
 Do not use SpO₂ sensor during MRI scanning. Conducted current may cause burns.
- If using SpO₂ sensor during full body irradiation, keep the sensor out of the irradiation field. If sensor is exposed to the irradiation, the reading might be inaccurate or the product might read zero for the duration of the active irradiation period.
- Do not place the product in an environment that exceeds the stated range.
- Do not modify the SpO₂ sensor in any way. Modification may affect performence and accuracy.

Notes

- Performance of the sensor may be compromised by motion. Try to keep the animal still and avoid the measured site suffering excessive motion.
- Always choose a site that is well perfused and will completely cover the sensor's detector window. If the sensor site has very low perfusion, the SpO₂ reading may be inaccurate. As tongue' perfusion is generally higher than the ears and other parts, so tongue is the preferred sensor site when performing the measurement.
- A proper sensor clip shall be selected according to different animals and application sites. Large and small clip can be adapted to different animals and application sites.
- Tight sensor may cause venous pulsation, obstructed blood circulation, pressure marks, pressure necrosis, artifacts and inaccurate measurement, while loose sensor may lead to erroneous optical alignment or falling off. If the sensor is too tight because the application site is too large or becomes too large due to edema, excessive pressure may result in venous congestion distal from the application site, leading to interstitial edema and tissue ischemia.
- Inspect the application site every two hours and change the application site when taking a long time continuous monitoring. Some animals may require more frequent inspections, such as animals with perfusion disorder or sensitive skin. Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering, burns, enous pulsation, obstructed blood circulation, pressure marks, pressure necrosis and so on
- Using the sensor in the presence of bright lights may result in inaccurate measurements. In such case, cover the sensor with an opaque material.

Applying SpO₂ sensor

sure to understand all warnings listed in the previous section before applying any SpO_2 sensor to the animal. Before use, verify whether the SpO2 sensor is intact, In case of any damage, do not apply it to the animal.

Applying SpO₂ sensor

- Clean the sensor and clip separately before and after each use.

 Open the clip by pressing with the thumb and forefinger, Place one of the sensor pad into the clip slot. Adjust the sensor pad until the sensor pad is fully engaged in the clip slot, as shown in Figure 1. So it is with another sensor pad. The sensor clip is now ready to be applied to the animals, as shown in Figure 2. Note: Be sure that the sensor pads are oriented as showin the illustrations. The optical components must face each other directly.
- Place the clip to the measurement site. Ensure that the sensor's optical components positioned on the center of the tongue, as shown in Figure 3.

 Note: The preferred application site for canine and feline animals is tongue. The other sites such as
- ear, lip, toe, prepuce or vulva can also be measured.

 Make sure that the sensor cable is positioned along the side of the animal's face and body to avoid
- entanglement with the animal, as shown in Figure 4.
- Connect the extension cable and the sensor. Then connect the extension cable to the pulse oximetry









Checking the Functionality of the Sensor

Replace the senor if the following situations occur when the sensor is connected to the instrument

- The "Sensor Fault" alarm occurs
- There is no "Sensor Off" alarm when the sensor is closed but not applied to the ear lobe
- The "Sensor Off" alarm occurs when the sensor is applied to the ear lobe

Start SpO2 monitoring only when you are sure that the sensor functions normally

Removing SpO₂ Sensor

For the comfort of the animal and to avoid damaging the sensor do not pull on the cable when removing the sensor and clip.

- Open the clip and remove the sensor and clip from the animal.
- Hold and release the senor pad from the clip slot.

- Failure to apply the sensor properly may cause inaccurate measurements. If the sensor cannot detect the pulse signal, it may be incorrectly positioned, or the application site is too thick or thin. If any of the situations occurs, reposition the sensor or try another sensor site. If the application site is covered with fur, shave the site and reapply the sensor.
- Do not use supplemental tape to adhere the clip and sensor directly to the application site, this can restrict blood flow and cause inaccurate measurements.
- To verify correct placement of the sensor on the site, manually take a puse rate reading from another site on the animal if the sensor is placed correctly, the manual measurement should correspond to the pulse rate reading displayed on the monitor.

Measurement Limitations

If you doubt the measured SpO₂, check animal's vital signs first. Then check the monitor and SpO₂ sensor. The following factors may influence the accuracy of measurement:

Ambient light

- Physical movement (animal and imposed motion)
- Diagnostic testing
- Low perfusion
- Electromagnetic interference, such as MRI environment
- Electrosurgical units
- Dysfunctional haemoglobin, such as carboxyhemoglobin (COHb)and methemoglobin (MetHb)
- Presence of certain dyes, such as methylene and indigo carmine
- Inappropriate positioning of the SpO₂ sensor, or use of incorrect SpO₂ sensor
- Drop of arterial blood flow to immeaurable level caused by shock, anemia, low temperature or vasoconstrictor.

Cleaning/Disinfection

Caution

- Do not immerse the connector of the sensor in water or any of the cleaning solutions or disinfectants.
- Exercise caution during cleaning/disinfection to avoid wetting the pins
- We recommend that the sensor be disinfected only when necessary as determined by your hospital's policy, to avoid long term damage to the sensor.
- Use cleaning solutions or disinfectants recommended by our company. Clean or disinfect the senor according to the method desicribed in operator's manual, otherwis, it might affect product performance or life.

Cleaning

- Clean the sensor or clip with cotton or soft cloth moistened with water.
- After cleaning, wipe off the water with a soft cloth.
- Allow the sensor or clip to air dry.

Disinfection

The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type (2%) liquid disinfectants (using glutaraldehyde-type (2%) liquid disinfectants to disinfect the clip, corrosion inhibitor must be added and blending).

- Clean the sensor or clip as instructed above.
- Disinfect the sensor or clip with cotton or soft cloth moistened with one of the recommended disinfectants.
- After disinfection, be sure to wipe off the disinfectant left on the sensor or clip with a soft cloth moistened with water.
- Allow the sensor or clip to air dry.

Specifications

Cable Length	1.3m
Wavelength Range	600nm - 1000nm
Maximum photic output	18 mW
Note: The information about the	a wayolongth range and maximum photic output concumption can be

especially useful to clinicians (for		notodynamic therapy is perform	
	SpO ₂	Pulse rate 20 - 254 bpm	
Measurement range	0% - 100% 70 to 100%: ±3% 0% to 69%: Not specified.		
Accuracy			±3 bpm
Environmental specifications	Temperature	Relative humidity	Barometric
Operating conditions	0°C - 50°C	15% - 95% (noncondensing)	57.0kPa - 107.4kPa
Storage conditions	-30°C - 70°C	10% - 95% (noncondensing)	16.0kPa - 107.4kPa

Symbols

0	Refer to instruction manual/booklet	愛	Latex free
M	Date of manufacture	MAIL TO SERVICE STATE OF THE PARTY OF THE PA	Manufacturer
LOT	Batch code	P/N	Part number
C€	Comply with the requirements of the Council Directive 93/42/EEC (Medical Device Directive).	IPX2	Protection against vertically falling water drops when ENCLOSURE tilted up to 15°
EC REP	Authorized representative in the European Community	Rx ONLY	Federal law (USA) restricts this device to sale by or on the order of a physician.
凉	Dispose of in accordance to your country's requirements		

Company Contact

www.mindrav.com

Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen 518057 P.R. China

Tel: +86 755 81888998 Fax +86 755 26582680 E-mail: service@mindray.com

EC-Representative: Shanghai International Holding Corp. GmbH (Europe) Address: Eiffestraße 80, 20537 Hamburg, Germany

0049-40-2513175 Tel:

0049-40-255726

551B兽用脉搏血氧传感器

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在下列条件都满足的情况下,迈瑞公司将对产品的安全性、可靠性和性能负责

- 按照《使用说明书》使用本产品。
- 非人为因素造成的产品损坏,人为因素是指不小心摔落、蓄意破坏等。

确实需要向迈瑞公司退货时,请联系迈瑞公司售后服务部,告知产品型号和系列号,并简述退货原 因。若产品的系列号模糊不可辨认, 退货请求将不予接受。

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产品介绍

适用范围

5518兽用脉搏血氧传感器由探头、电缆线、连接器和两个不同尺寸的夹子构成。

5518兽用脉搏血氧传感器为重复用传感器,与具有血氧测量功能的兽用设备配套使用,对犬科及 猫科类动物的血氧饱和度及脉率进行点测或连续测量。

本产品必须与本公司指定的具有血氧测量功能的兽用设备配套使用。使用者有责任在使用前阅读 设备(包括配附件)的使用说明书或与本公司联系咨询,以确认本传感器与设备(包括配附件)的匹配 性。使用者必须是经过专业培训的临床医护人员。否则,可能损坏附件或设备,或给动物带来伤害。

请根据设备的接口类型选择合适的延长电缆。

禁忌症

对动物进行持续的长时间监测时,应根据动物的皮肤状况定期检查和更换测量部位,应至少每2 小时检查一次。个体皮肤的差异性会影响皮肤对探头的耐受能力,因此对一些特殊的动物更应该尽可 能多的更换测量部位。

警告

- 使用前请检查传感器及其电缆,如发现传感器及电缆有损坏、污染或材料变质迹象,或发现包装 破损, 请不要再将其用于动物的监护。
- 如发现夹子有磨损、破裂或者弹簧弹性失效, 应更换夹子。
- 如要废弃, 请按当地相关法规或医院的废物处理制度进行, 不可随意丢弃。
- 为减少电外科设备对测量的影响,不可将传感器电缆放置在靠近电外科设备电源线的位置。
- 本产品只能与指定的设备配合使用。使用前请阅读设备的使用说明书,以确认本产品与设备的匹 配件.
- 小心布置传感器电缆和连接电缆,避免缠绕动物或使动物窒息。
- 6 请勿长时间大幅度弯折电缆。
- 不可在进行磁共振成像 (MRI) 扫描时使用传感器, 否则感应电流可能造成灼伤。 .
- 如果在全身放射治疗过程中使用传感器,请将传感器安置到放射区域之外。如果将传感器暴露在放射区域,会导致读数不准确,或在有效放射时间段内的读数为零。 8
- 请勿将传感器置于超出声称规格的环境中。
- 不可以任何方式修改或更改传感器。更改或变动可影响传感器的性能和/或准确性。

注意

- 测量部位应避免频繁移动, 应尽量使动物保持安静, 减少移动。
- 测量部位应尽量选择灌注良好并且能够完全覆盖传感器的部位。如果测量部位的灌注过低,则可 能会导致脉搏血氧饱和度测量不准确。舌头的灌注一般比耳朵等部位高, 所以测量时首选舌头作 为测量部位,其他部位有时会因为灌注过低而无法准确测量。
- 应根据不同的动物以及不同的测量部位选择合适的传感器夹子。大、小夹子可适应不同的动物和测 量部位。
- 夹子夹持得太紧将会导致静脉搏动、血液循环受阻、压迫痕迹、压迫性坏死、位差、测量不准确; 如果太松就会有损光学对准,甚至会脱落的情况;如果因为安放部位过大,或是由于安放部位水 肿变大,导致传感器太紧,过大的压力就会在安放部位的远端导致静脉淤血,造成间质水肿和组 妈缺血
- 对动物进行持续的长时间监测时, 应至少每2小时检查并更换测量部位。某些动物可能需要更频 繁的检查,如具有灌注障碍或皮肤敏感的动物。因为持续的长时间的监控可能增加不可预料的皮 肤变化,如过敏、变红、起泡、静脉搏动、血液循环受阻、压迫痕迹、压迫性坏死等情况。
- 强光会导致测量不准确。若光线较强,请使用不透光材料遮盖传感器。

使用前,确保已经理解了列出的所有注意事项。使用前,应检查传感器与夹子是否有脏污或锈渍。 如果有, 应在清洁或擦除后再行使用。必要时, 请更换传感器。

- 1. 每次使用之前或之后,应分别对传感器和夹子进行清洁。
- 张开夹子,如图1所示将探头放入夹子凹槽内。将探头的线缆对准夹子凹槽的缺口,然后将探 头按入夹子的凹槽内。安装完成后如图2所示。

注意: 确保将探头按照图示方向进行安装。不可将探头的光学组件方向装反。

3. 将夹子安放到测量部位,如图3所示使探头的光学组件对准舌头的正中部位。

注意:猫科及犬科类动物的最佳测量部位为舌头。耳朵、嘴唇、脚趾、包皮以及阴户等部位也 可进行测量。

- 确保传感器线缆沿着动物的脸颊或身体正确放置,避免发生缠绕(如图4所示)。
- 根据设备的使用说明书,将传感器和主电缆连接,并连接到设备。



图1



图2





传感器连接检查

传感器连接到设备后, 若出现有以下情况, 则说明传感器异常, 需更换传感器;

- 设备有"传感器故障"报警。
- 当传感器闭合且未接测量部位时,设备无"传感器脱落"报警。
- 当传感器正确放置在测量部位后,设备有"传感器脱落"报警。 传感器连接无异常后, 方可对动物进行测量。

移除传感器

为了不损害传感器并避免造成动物的不适,在移除传感器及夹子的时候应避免直接拉扯电缆。

- 张开夹子,将传感器及夹子从动物身上移除。 将探头从夹子凹槽中推出。
- 2.

注章

- 脉搏血氧传感器安放位置不当可能影响测量的准确性。如果传感器不能准确的检测出脉搏信号, 0 则可能是测量部位的偏差,或者测量部位太厚或太薄。出现上述任何一种情况时,请重新放置传 感器或者尝试另外一个测量部位进行测量。如果测量部位被毛皮覆盖,应剪除后再进行测量。
- 不要额外采用绑带去固定夹子及传感器, 因为这将影响血液的流动而导致测量的不准确。
- 为了确认传感器的正确佩戴, 应从动物的其它部位手动进行脉搏的测量, 如果从监护仪上读取的 数据与手动测量的相符,则说明传感器佩戴正确。

测量影响因素

如果您怀疑测量结果的准确性, 请首先采用其它方法检查动物的生命体征, 然后再检查监护仪及 脉搏血氧探头。测量过程中,以下因素可能会影响测量的准确性:

- 外界光辐射
- 身体移动(动物主动或被动的移动)或抖动 \Box
- - 弱灌注
- 电磁场影响, 如核磁共振设备 П
- 电外科设备
- 非功能血红蛋白的浓度,如碳氧血红蛋白(COHb)和正铁血红蛋白(MetHb)
- 定染料的存在,如亚甲基兰、胭脂靛
- 脉搏血氧传感器安放位置不合适,或使用了不正确的脉搏血氧传感器
- 休克、贫血、低温或应用了血管收缩药物等导致动脉血流降低到无法测量的水平

清洁/消毒

小心

- 不可将传感器连接器浸泡在水中或消毒剂中。
- 不要弄湿传感器连接器的针脚。 .
- 频繁地对传感器进行消毒会对其造成损害。建议根据医院的规定, 在需要时才对传感器进行消毒。
- 请使用本公司推荐的清洁消毒剂并按照说明书提供的方法对本产品进行清洁消毒, 否则可能会影 响产品性能或寿命。

清洁

- 1. 用沾有清水的棉球或软布擦洗传感器或夹子。
- 2. 清浩完毕后, 生用布将传感器或夹子擦干。
- 3. 将传感器或夹子放置在阴凉的环境下晾干。

消毒

推荐使用的消毒剂包括: 70%乙醇、70%异丙醇、2%戊二醛溶液(使用戊二醛溶液对夹子进行消 毒时, 需加入消毒剂厂商提供的缓蚀剂混匀后再消毒)。

- 1. 消毒前,清洁传感器或夹子。
- 2. 用棉球或软布沾适量的消毒剂,擦洗传感器或夹子。
- 3. 用沾有清水的软布擦除残留在传感器或夹子上的消毒剂。
- 4. 将传感器或夹子放置在阴凉的环境下晾干。

产品规格

线缆长度	1,3m	
传感器波长范围	600nm - 1000nm	
最大光输出功耗	18 mW	
注意:波长范围和	最大光输出功率的数值可以帮助临床医生进行判断,	例如光动力的治疗方法。

	脉搏血氧饱和度		脉率
测量范围	0% - 100%	0% - 100% 70 - 100%: ±3% 0% - 69%: 精度不予定义	
測量精度	1000000		
环境规格	温度	湿度	大气压力
工作环境	0°C - 50°C	15% - 95% (非冷凝)	57.0kPa - 107.4kPa
贮运环境	-30°C - 70°C	10% - 95% (非冷凝)	16.0kPa - 107.4kPa

符号

0	参考说明书或随机资料说明	愛	不含天然乳胶
M	生产日期		生产商
LOT	批次代码	P/N	物料编码
C€	符合欧盟医疗设备指令93/42/EEC	IPX2	15°防滴
[EC REP	欧共体授权代表	Ā	不得将废弃的电气电子设备当作未 分类整理的城市废物处理,应另行 收集。有关设备报废的信息请联系 制造商的授权代表

售后服务单位

传真:

单位名称: 深圳迈瑞生物医疗电子股份有限公司

单位地址: 深圳市南山区高新技术产业园区科技南十二路迈瑞大厦1-4层

邮政邮编: 518057 网址: www.mindrav.com 24小时服务热线: 4007005652 电话:



