MR6401 CPR Sensor

Instructions for Use

CE 2797

EC REP

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Product Introduction

The CPR sensor is intended to provide real-time CPR feedback for patients at least 8 years old or above 25kg weight. It displays the depth and rate of chest compression as well as interruption time. The CPR sensor should be used in healthcare facilities by clinical professionals trained in CPR and use of the device.

Safety Information

WARNING

- **Do not use the CPR sensor on patients under 8 years old or below 25kg weight.**
- **The CPR sensor is used for single patient at a time.**
- **The CPR sensor can be use together with Mindray defibrillator and Mindray monitor supporting the CPR function.**
- **When the CPR sensor is used together with a defibrillator, make sure to follow the defibrillator manufacturer's instructions. Stop compressions, remove hands from the CPR sensor and remain clear of all patient contact during defibrillation or when otherwise required, in accordance with a proper defibrillation protocol.**
- **When performing CPR on a patient lying on a mattress, a backboard must be used to limit the amount of compressed depth which is absorbed by the mattress. Depending on characteristics of the mattress, backboard and patient, the compensation depth does not guarantee that the patient chest is compressed by 50 mm.**
- **The battery indicator lighting in red indicates a low battery. To ensure the CPR sensor is ready for operation in an emergency treatment, you should charge the battery in time. Do not interrupt CPR when the battery indicator lighting in red during the emergency treatment.**
- **Do not interrupt CPR in any case, such as low battery or self-test error. Continue CPR without feedback from the CPR sensor.**
- **The CPR sensor can bear at most 80kg applied force. Applying force over this limit may result in sensor damage.**
- **The CPR sensor is not intended for use in a moving environment, such as an ambulance. If used during patient transport, the CPR sensor may provide inaccurate feedback. If CPR is indicated in a moving environment, do not rely on the CPR sensor depth feedback during such conditions.**
- **Do not use the CPR sensor in conjunction with any mechanical or automated compression device.**
- **Do not use the CPR sensor on top of defibrillation pads.**
- **Cleaning or disinfection should be performed on the CPR sensor housings after each use.**
- **If there are signs of fluid entry, stop using the CPR sensor immediately and contact your service personnel.**
- **Do not open the CPR sensor housings. All servicing and future upgrades must be carried out by trained and authorized personnel.**

- **Replacing the battery if the CPR sensor is configured with is not allowed. It must be replaced by your service personnel.**
- **Properly performed CPR may result in fracturing of the patient's ribs, external chest wall bruising or abrasion.**
- **If there are externally visible damages on the CPR sensor or the sensor cable, stop using the CPR sensor immediately and contact your service personnel.**

CAUTION

- **Magnetic and electrical fields are capable of interfering with the proper performance of the CPR sensor. For this reason make sure that all external devices operated in the vicinity of the CPR sensor comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
- **Always carry the CPR sensor properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**
- **Dry the CPR sensor immediately in case of rain or water spray.**
- **At the end of its service life, the CPR sensor, as well as CPR sensor cable, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal, please contact us.**
- **Dispose of the package material as per the applicable waste control regulations. Keep it out of children's reach.**

Battery

WARNING

- **Check the battery indicator regularly.**
- **The battery indicator lighting in red indicates a low battery. To ensure the CPR sensor is ready for operation in an emergency treatment, you should charge the battery in time. Do not interrupt CPR when the battery indicator lighting in red during the emergency treatment.**

Basic Operations

WARNING

- **Do not apply the CPR sensor to an open wound or recent incision site.**

Cleaning/Disinfection

WARNING

- **Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).**

- **When cleaning or disinfecting the CPR sensor, avoid the CPR sensor connector.**

Product Specifications

WARNING

- **The CPR sensor may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges.**

Safety Classifications (according to IEC 60601-1)	Degree of protection against electrical shock	Type CF defibrillation proof	
	Type of protection against electrical shock	■ Used alone: Class II, equipment energized from an internal electrical power source. ■ Used together with the defibrillator or monitor: Class II, equipment energized from a specific or internal electrical power source.	
	Degree of protection against harmful ingress of water	IP55	
	Drop height	1.5 m	
	Degree of protection against hazards of explosion	The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air with oxygen or nitrous oxide.	
	Mode of operation	Continuous	
Evironmental Specifications		**Operating conditions**	**Storage conditions**
	Temperature	0°C to 50°C	-30°C to 70°C
	Relative humidity	10% to 95%, non-condensing	10% to 95%, non-condensing
	Barometric	57.0kPa to 106.2kPa	57.0kPa to 106.2kPa
Power Specifications	Input voltage	5 to 12V ⎓	
	Power consumption	Not applicable	
Battery Specifications (optional)	Capacity	≥230 mAh	
	Voltage	3.8 V	
	Run time	■ At least 3 hours when the CPR sensor works continuously at a temperature of 25°C±5°C with a fully-charged battery. ■ At least 30 days when the CPR sensor is in the sleeping status. ■ At least 1 hour after the battery indicator is in red light.	
	Charge time	At most 1.5 hours to a full charge when a depleted battery is charged at a temperature of 25°C±5°C.	

Physical Specifications	Sensor size	< 150mm × 63mm × 20m	
	Compression area	< 92mm × 53mm × 19mm	
	Adhesive mount area	≤ 98mm × 45mm	
	Sensor weight	≤ 220g (including battery, without CPR sensor cable)	
Measurement Specifications	Compression depth	Measurement range	0.0 to 8.0 cm
		Effective range	1.5 to 8.0 cm
		Accuracy	±0.5 cm or ±10%, whichever is greater
		Resolution	0.1 cm
		Refreshing rate	≥ 0.5 Hz
	Compression rate	Measurement range	40 to 160 cpm (compressions per minute)
		Effective range	40 to 160 cpm (compressions per minute)
		Accuracy	±2 cpm (compressions per minute)
		Resolution	1 cpm
		Refreshing rate	≥ 0.5 Hz
	Interruption time	Measurement range	0 to 300 s
		Effective range	0 to 300 s
		Resolution	1 s
		Refreshing rate	≥ 0.5 Hz

EMC

The device meets the requirements of IEC 60601-1-2. For more information, see the operator's manual of the defibrillator or monitor used together with this device.