

CPRmeter 2

User Guide





www.laerdal.com

Contents

Intended Use	4
Indication for Use	4
Important Information	5
Items Included	6
Overview	8
Before Use - Insert Batteries	10
Before Use - Apply Patient Adhesive	11
Getting Started	12
CPRmeter 2 Placement	13
Feedback Display Overview	15
Compression Feedback	16
Depth On Soft Surface Rate Compression Counter Inactivity	16 17 18 18 19
Debriefing	20
Battery Indicator	22
Maintenance	23
After Each Use Cleaning Disinfection Storing the CPRmeter 2 Between Use Customer Service Indicator	23 24 24 25 25
Specifications	26
Symbol Glossary	29
Regulatory Information	31

Intended Use

The CPRmeter 2 with O-CPR® technology is a small, lightweight device powered by a replaceable battery. The device is intended for use by responders who have been trained in CPR and use of the CPRmeter 2.

When attached to the bare chest of a suspected victim of SCA, the CPRmeter 2 provides real-time feedback on CPR compressions in accordance with current CPR guidelines. It displays CPR feedback indicators for depth, release, and rate of chest compressions. It also counts the number of compressions in a series, and provides notification of lack of expected CPR activity.

If in doubt about the appropriateness for use, perform CPR without using the CPRmeter 2.

Indication for Use

The CPRmeter 2 is used as a guide in administering cardiopulmonary resuscitation (CPR) to a suspected sudden cardiac arrest (SCA) victim at least 8 years old.

Important Information

/ Warning

The CPRmeter 2 is not intended for use on SCA victims under 8 years old.

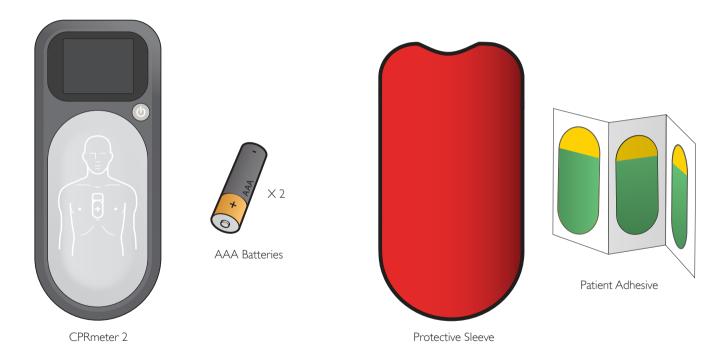


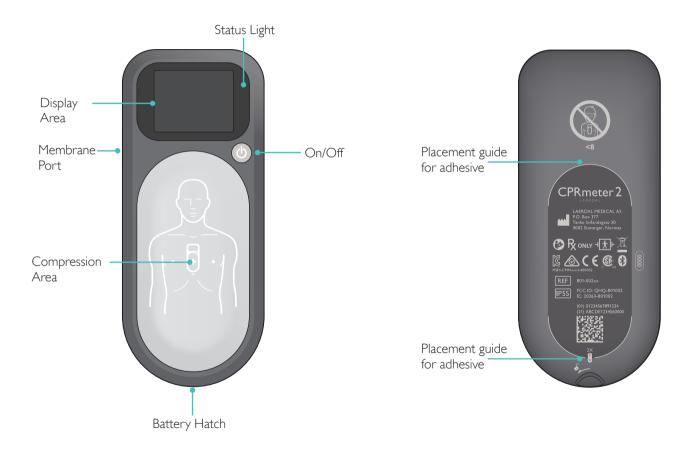
Note

CPR cannot assure survival, no matter how well it is performed. In some patients, the underlying problem causing the cardiac arrest is not survivable despite any available care.

Rx Only (USA)

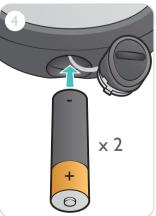
Caution: Federal law restricts this device to sale by or on the order of a physician.

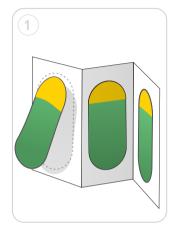














- Ensure Patient Adhesives are within their expiration date.
- Adhesives should be removed from the device and disposed of after 2 years.





Before Use - Apply Patient Adhesive

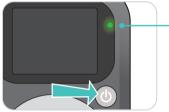
Getting Started

CPRmeter 2 Placement



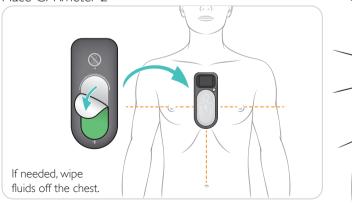
- Remove the device from its protective cover.
- Ensure the patient is on a firm surface.
- Remove clothing from the patient's chest.

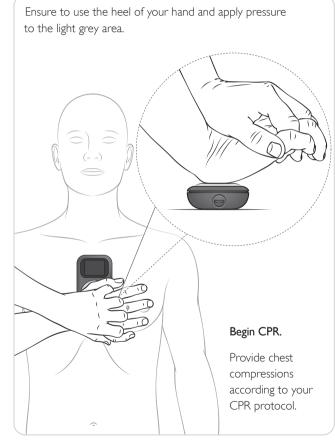
Turn On



Status Light turns green for a few seconds, when CPRmeter 2 is turned on.

Place CPRmeter 2



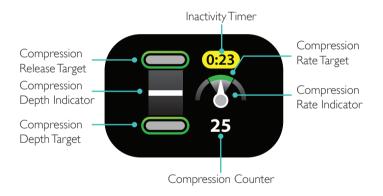


<u>∧</u> Cautions

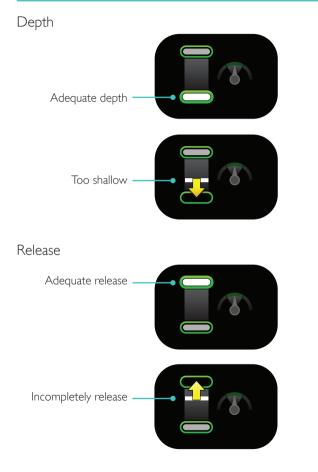
- If the CPRmeter 2 moves during use, re-position it to the center of the chest, as shown.
- If difficulty is encountered in applying the device, do not delay initiation of CPR. Remove the device and begin compressions.
- If the device's status light is orange and the CPRmeter display is dark, stop using the CPRmeter and continue CPR. Contact Laerdal for technical support after the event.

<u>∱</u> Warnings

- Do not use the device in conjunction with any mechanical or automated compression device.
- Do not use the device on top of defibrillation pads, unless the manufacturer of the defibrillator and the defibrillation pads has explicitly stated that the device can be used in such manner.
- Do not delay CPR. If you experience any problems using the device, continue CPR without it. If the device appears to be damaged, do not use.



Compression Feedback



On Soft Surface

If the CPRmeter 2 detects a compression that exceeds 70 mm (2.75"), it will show the depth indicator below the target area. If a specific CPR event requires CPR to be performed on a patient lying on a mattress, slide a backboard under the patient and compensate for the mattress softness by ensuring that for each chest compression the area below the compression depth target lights up.

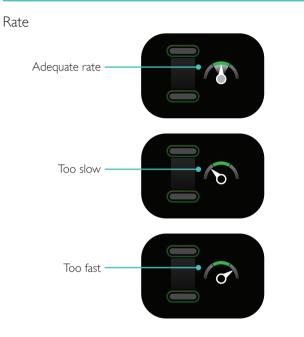


Marning

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 depth compensation does not guarantee that the patient chest is compressed by 50 mm (2").

Compression Feedback





Compression Counter

When compressions are started a counter will display grey up to 25 compressions.





During a cycle of 30 compressions, the counter changes to solid white between 25 and 30 compressions. Beyond 30 compressions, the counter digits flash solid white for every tenth compression.

Without a compression the counter is reset after 3 seconds.

Inactivity



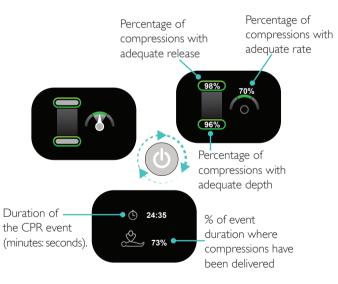
- After 3 seconds the CPRmeter 2 displays an inactivity timer which counts the seconds since the last compression.
- After 20 seconds since the last compression, the inactivity timer starts flashing.
- After 1 minute, the CPRmeter 2 display fades down to conserve battery power. The display is restored when a new compression is delivered.

Debriefing

O-CPR[®] Ouick Review

The CPRmeter 2 can display CPR performance statistics for the last CPR event. When the device is turned on, press the On/Off button once to activate Q-CPR Quick Review. The statistics are shown over two displays.

Press the On/Off button once to cycle to the next display.



The CPRmeter 2 reverts to Compression Feedback mode if a compression is delivered.



Notes

- The CPR event statistics are stored when the CPRmeter 2 is turned off. When turned on again, the statistics from the last stored CPR event can be reviewed
- When the CPRmeter 2 is used in a new CPR event, the O-CPR Quick Review will display the current event's statistics.
- CPR performance statistics are only calculated if at least 10 compressions have been delivered.

Wireless Data Transfer

The CPRmeter 2 has Bluetooth Smart functionality for uploading complete event data to an external device, like a PC. Bluetooth can also be used to stream live CPR performance data during training.



To connect a device, go to the MiniEvent Review screen by pushing the On/Off button. The status light will flash blue indicating that Bluetooth is on and available for connection. When connected to a device, the flashing blue light turns steady. The CPRmeter 2 is now ready to transfer CPR performance data.

Note

Ensure Bluetooth connectivity is disabled during clinical use.

Battery Indicator

Battery Monitoring

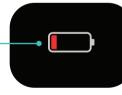
The CPRmeter 2 continuously monitors the power of its battery. On a routine basis, particularly after periods of non-use, check the CPRmeter 2 battery status by switching on and checking if the low battery icon is displayed.

If the remaining power is estimated to be less than that required for a 30 minute CPR event, the visual indicators signal that the battery should be replaced before the next use.



A small low-battery icon appears when the CPRmeter 2 is being turned on.

A large low-battery icon appears when the CPRmeter 2 is being turned off.



Routine Maintenance

- 1. On a routine basis check the battery status (as described).
- 2. Replace the battery at least every 2 years.
- 3. On a routine basis, check that the CPRmeter 2 has a patient adhesive in place and that the liner remains on it. Replace the patient adhesive at least every 2 years if it is not used.

🗒 Note

If the remaining battery power during use becomes too low to sustain further operation, the low-battery icon is shown for 10 seconds and then the CPRmeter 2 turns itself off.

Marning

Do not interrupt CPR to replace the battery. Continue CPR without feedback from the CPRmeter 2.

After each Use

After use on a patient, the CPRmeter 2 may be contaminated and should be handled appropriately.

- 1. Place the contaminated CPRmeter 2 in a plastic bag until it can be cleaned (do not insert a contaminated CPRmeter 2 into its casing).
- 2. If it is visibly soiled, wipe the CPRmeter 2 with a soft cloth or paper towel to remove as much contamination as possible.
- 3. Remove the Patient Adhesive from the back of the CPRmeter 2.
- 4. Clean the CPRmeter 2 as described under Cleaning and Disinfection. Proper cleaning is required to achieve disinfection.
- 5. Check the exterior of the CPRmeter 2 for signs of damage. Contact Laerdal to arrange for replacement if needed.
- 6. Apply a new Patient Adhesive to the device as described in Before Use - Apply Patient Adhesive.

If the device has been used in a clinical situation, clean it as follows:

If the CPRmeter 2 has been used in a training situation, it may be

 Prepare the cleaning solution by mixing (5 ml) of mild dishwashing liquid in 4 l of warm tap water (40-50 °C)

wiped using an alcohol wipe (70% ethanol solution).

- 2. Submerge a small brush (e.g. toothbrush) in the cleaning solution and scrub the device for a minimum of 2 minutes.
- 3. If the membrane port is clogged, use the brush to remove any obstruction.
- 4. Wipe the exterior with a soft cloth dampened in lukewarm water (22-40 °C).

Disinfection

- Disinfect the exterior using a 0.55% solution of orthophthalaldehyde. Spray the solution on to cover all exterior surfaces, and allow to sit for a minimum of 12 minutes. An alternative disinfection agent is isopropyl alcohol (70% solution). If necessary respray to account for evaporation of isopropyl alcohol.
- 2. Wipe the exterior with a clean soft cloth dipped in water a minimum of three times to remove all traces of disinfectant agent. Allow to dry completely.

A Caution

Do not immerse the CPRmeter 2 in water, hold it under running water, or allow moisture to penetrate it. Do not sterilize the CPRmeter 2.

Storing the CPRmeter 2 between Use

Store the CPRmeter 2 in its protective cover to shield the display screen from scratches and to protect the patient adhesive from damage. Ensure that the On/Off button can not be inadvertently activated during storage.

Customer Service Indicator

If the Customer Service Indicator appears on the CPRmeter 2 at shutdown, please contact your local Laerdal representative for further instructions.



Cleaning

CPR Targets

Category	Specification
Compression Depth Target	> 50 mm (2'') Depth accuracy: ±10%
Compression Release Target Force	< 2.5 kg (5.5 lbs) Force accuracy: ±1.5 kg (+3.3 lbs, - 3.3 lbs)
Compression Rate Target	100 to 120/min ± 3/min

CPRmeter 2 [REF 801-00233]

The CPRmeter 2 meets the performance requirements of IEC 60601-1, 2nd and 3rd edition.

Category	Specification		
Dimensions	153 mm × 64 mm × 25 mm (6.0'' × 2.5'' × 1.0'')		
Weight	163 g (5.7 oz) (excluding batteries)		
Battery	2 x 1.5V Size AAA (LR03)		
Temperature	Transport and Storage: -20 °C to 70 °C (-4 °F to 158 °F) Operation: 0 °C to 40 °C (32 °F to 104 °F) Sealing: Meets ISO/IEC 60529 class IP55 Product temperature can reach 60 °C (140 °F)		
Relative Humidity	Transport: 5% to 95% Storage: 5% to 75% Operation: 5% to 95%		
Atmospheric Pressure (Atm.p.)	Transport, Storage and Operation: 1014 to 572 mbar (1014 to 572 hPa)		
Electromagnetic Compatiblity	Meets IEC 60601-1-2 and RTCA/DO-160F Section 21 Category M		

CPRmeter Patient Adhesives [REF 801-10850]

Category	Specification		
Dimensions	39 mm x 90 mm (1.5'' x 3.5'')		
Temperature	Storage: -20 °C to 70 °C (-4 °F to 158 °F) Operation: 0 °C to 50 °C (32 °F to 122 °F)		
Relative Humidity	Storage: 0% to 75% Operation: 0% to 95%		
Material	Foam pad with biocompatible adhesive on each side.		
Shelf Life	2 years when applied to the CPRmeter 2 or 4 years in unopened package. Do not exceed the expiration date on the packaging.		

Environmental Considerations

Product	Information
CPRmeter 2	The CPRmeter 2 contains electronic components. Dispose of it at an appropriate recycling facility in accordance with local regulations.
CPRmeter Patient Adhesive	The used Patient Adhesive may be contaminated with body tissue, fluid, or blood. Dispose of it as infectious waste.

Symbol	Definition
CE	The product is in compliance with the essential requirements of Council Directive 93/42/EEC as amended by Council Directive 2007/47/EC and Council Directive 1999/5/EC.
	Compliance with applicable U.S. and Canadian safety standards has been certified by Canadian Standards Association.
(2)	These CPRmeter 2 patient adhesives are disposable and are for single patient use only. Do not re-use. Re-use will lead to increased risk of cross contamination, and/or degradation of adhesive performance.
⊣∱⊦	Defibrillation protection. The CPRmeter 2 is defibrillation protected, type BF patient connection.
	Manufacturer
X	Dispose of in accordance with your country's requirements
REF	Reference order number
IP 55	The CPRmeter meets IEC 60529 class IP55
	Expiration date for patient adhesives
LATEX	Not made with natural rubber latex
\triangle	Warning/Caution symbol
1	Temperature limitations for transport/storage of the adhesives

Symbol Glossary

= #	Contains number of CPRmeter 2 patient adhesives shown as "#."
P	Consult Directions for Use
R	Lift here to peel off the patient adhesive liner and apply to patient's bare chest
	Not for use on children under 8 years old
	Australian RCM mark
\ast	Bluetooth symbol
	Federal law restricts this device to sale by or on the order of a physician
Ĭ.	KC symbol (for Korea)

A Warning identifies conditions, hazards, or unsafe practices that can result in serious personal injury or death.

A Caution identifies conditions, hazards, or unsafe practices that can result in minor personal injury or damage to the CPRmeter 2.

M Warnings

- When the CPRmeter 2 is used together with a defibrillator, make sure to follow the defibrillator manufacturer's instructions. Stop compressions, remove hands from the CPRmeter 2 and remain clear of all patient contact during defibrillation or when otherwise required, in accordance with a proper defibrillation protocol.
- The CPRmeter 2 is not intended for use in a moving environment, such as an ambulance. If used during patient transport, the device may provide inaccurate feedback. If CPR is indicated in a moving environment, do not rely on the depth feedback during such conditions. It is not necessary to remove the device from the patient.
- Do not practice by using the CPRmeter 2 on a person. It may be used with a training manikin or simply on a compliant surface for practice.
- Properly performed CPR may result in fracturing of the patient's ribs.¹ If rib integrity has been compromised, continue to provide CPR in accordance with your local protocol.
- Properly performed CPR may result in chest injuries¹ e.g. external chest wall bruising or abrasion.
- Do not rely on CPRmeter 2 feedback during aircraft ascent and descent, as its accuracy is reduced in such conditions.

¹ Black CJ, Busuttil A, Robertson C. Chest wall injuries following cardiopulmonary resuscitation. Resuscitation. 2004;63:339 –343.

Regulatory Information

<u>∧</u>Cautions

- Do not apply the CPRmeter 2 to an open wound or recent incision site.
- The device is designed to be used only with Laerdal-approved accessories and may perform improperly if non-approved accessories are used. Do not attempt to modify the device in any way.
- Use only model 801-10850 Patient Adhesives with the CPRmeter 2.

Note

Changes or modifications not expressly approved by Laerdal Medical could void the user's authority to operate the equipment.

Recommendation

Responders should receive training, including regular refresher training, in use of the CPRmeter 2. When training with the device on a CPR manikin, disable or ignore feedback from the manikin.

WEEE

This appliance is marked according to the European directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE).

By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product.

The symbol on the product indicates that this appliance may not be treated as household waste. Instead it shall be handed over to the applicable collection point for the recycling of electrical and electronic equipment. Disposal must be carried out in accordance with local environmental regulations for waste disposal.

For more detailed information about treatment, recovery and recycling of this product, please contact your local city office, your household waste disposal service or the Laerdal representative where you purchased the product.

FCC

Federal Communications Commission Statement and Industry Canada Statements

This device complies with part 15 of the FCC rules and RSS-210 of the Industry Canada rules. Operation is subject to the following two conditions:

- 1. This device may not cause harmful interference, and
- 2. this device must accept any interference received, including interference that may cause undesired operation.

Ce dispositif est conforme à la norme CNR-210 d'Industrie Canada applicable aux appareils radio exempts de licence. Son fonctionnement est sujet aux deux conditions suivantes:

- 1. Le dispositif ne doit pas produire de brouillage préjudiciable, et
- 2. ce dispositif doit accepter tout brouillage reçu, y compris un brouillage susceptible de provoquer un fonctionnement indésirable.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Consult the dealer or an experienced radio/TV technician for help.

FCC ID: QHQ-801002

IC ID: 20263-801002

The term "IC" before the equipment certification number only signifies that the Industry Canada technical specifications were met.

Regulatory Information

Electromagnetic Conformity

Guidance and manufacturer's declaration: The CPRmeter 2 is intended for use in the electromagnetic environment specified in the tables below. The user of the CPRmeter 2 should assure that it is used in such an environment.

Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF CISPR 11	Group 1 Class	The CPRmeter 2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The CPRmeter 2 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	There are no special requirements with respect to electrostatic discharge.
Power Frequency (50/60/400 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial/ hospital environment. There are no special requirements for non-commercial/ non-hospital environments.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the CPRmeter 2, than is absolutely necessary. †,‡ The recommended separation distances for various transmitters and the CPRmeter 2 are shown in the following table. Interference may occur in the vicinity of equipment marked with the following symbol:

 \dagger The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,660 MHz to 40,700 MHz.

‡ Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CPRmeter 2 is used exceeds the applicable RF compliance level above, the CPRmeter 2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CPRmeter 2.

Recommended separation distances between portable and mobile RF communications equipment and the CPRmeter 2

The CPRmeter 2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CPRmeter 2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CPRmeter 2 as recommended below, according to the maximum output power of the communications equipment.

Electromagnetic Emissions

Rated maximum output power of		Separation distance according to frequency of transmitter [m]		
transmitter [W]	150 kHz to 80 MHz	80 MHz to 800 MHz d=1.2√P	800 MHz to 2.5 GHz d=2.3√P	
0.01	NA	0.12	0.23	
0.1	NA	0.38	0.73 0,72?	
1	NA	1.2	2.3	
10	NA	3.8	7.3 7,28?	
100	NA	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1.At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2.The ISM (industrial, scientific and medial) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13, 567 MHz; 26,957 MHz to 27,283 MHz; and 40,660 MHz to 40,700 MHz.

NOTE 3. An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

NOTE 5. Transmitters/antennas of this power-level are most likely mounted on an emergency vehicle chassis. The distances cited here are for open field. For an external antenna, the separation distance is most likely shorter:

Warranty

The Laerdal CPRmeter 2 has a one-year limited Warranty. Refer to the Laerdal Global Warranty for terms and conditions.

About this edition

The information in this applies to the model 801-00233 CPRmeter 2. This information is subject to change.

The CPRmeter[™] with Q-CPR[®] is protected by U.S. and International registered patents.The design of CPRmeter[™] and its feedback symbols are protected in several jurisdictions under international design registrations.

 $\mathsf{CPRmeter}^{\mathsf{TM}}$ and $\mathsf{Q}\text{-}\mathsf{CPR}^{\texttt{R}}$ are trademarks or registered trademark of Laerdal Medical AS.

Laerdal[®] is a registered trademark of Laerdal Medical AS. © 2015 Laerdal Medical AS. All rights reserved.

P.O. Box 377 Tanke Svilandsgate 30, 4002 Stavanger, Norway T: (+47) 51511700 20-09504 Rev A

Printed in Norway.



www.laerdal.com