

cprINSIGHT® analysis technology

Sudden cardiac arrest (SCA)

Most people don't anticipate witnessing a cardiac arrest or participating in a resuscitation in a public setting. SCA affects more than 347,000 adults and 7,000 children in the United States each year.¹ When SCA strikes, early defibrillation with an automated external defibrillator (AED) like the LIFEPAK® CR2 AED, is essential to treat potentially fatal heart rhythms. However, it is also crucial to provide as much continuous CPR as possible to give the victim the best chance of survival. The American Heart Association (AHA) has recognized the need to educate the public on recognition of SCA, prompt provision of CPR and use of an AED to encourage bystander response and increase survival rates for victims of SCA.

"CPR is the single-most important intervention for a patient in cardiac arrest, and chest compressions should be provided promptly."²

2020 AHA Guidelines for cardiopulmonary resuscitation and emergency cardiovascular care

When SCA occurs, delivering chest compressions essentially takes over for the victim's failing heart. Given that many victims do not survive SCA, the AHA has established more vigorous guidelines for CPR:²

- Push hard at least two inches
- Push fast at a rate of 100-120 compressions per minute
- Allow the chest to fully recoil before pushing down again
- Minimize interruptions in compressions
- Change compressors every two minutes or sooner, if fatigued

Lay rescuer CPR for victims of SCA improves survival rates two/threefold.² When it comes to CPR, continuous is better. cprINSIGHT analysis technology can increase CPR time during a resuscitation.

What is cprINSIGHT analysis technology?

All AEDs have cardiac rhythm identification technology that allows the device to determine if the victim's cardiac rhythm is shockable or non-shockable. Traditionally, this technology requires the rescuer to stop chest compressions to analyze the cardiac rhythm, usually around 10-20 seconds. In Stryker's LIFEPAK devices, that technology is the Shock Advisory System™ (SAS).

cprINSIGHT analysis technology is available exclusively on the LIFEPAK CR2 that works in conjunction with SAS.

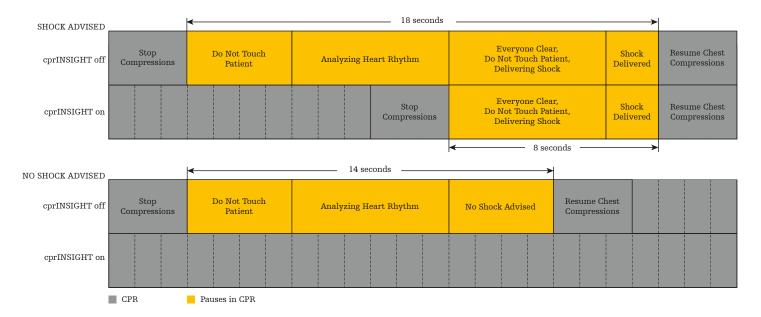
- When the LIFEPAK CR2 is turned on and the electrode pads are applied to the victim, the rescuer will be prompted to not touch the patient to allow the device to analyze the cardiac rhythm. The initial analysis uses SAS to quickly determine if the victim is in a shockable rhythm and deliver a shock. Studies show early defibrillation for shockable cardiac arrest rhythms drastically increases a victim's chances for survival.^{2, 3, 4}
- 2. After the initial analysis by SAS, and a shock is delivered (if applicable), the rescuer will be prompted to begin chest compressions. Subsequent rhythm analyses will be conducted during chest compressions by cprINSIGHT analysis technology at the end of two-minute CPR cycles. cprINSIGHT accurately analyzes the victim's cardiac rhythm during ongoing chest compressions in most cases and will reach a decision of:
 - Shockable (S)
 - Non-shockable (NS)
 - No decision (ND)

If cprINSIGHT determines the rhythm is shockable, the rescuer will be prompted to stop chest compressions, clear the victim, deliver the shock and immediately continue chest compressions. If the rhythm is determined to be non-shockable, the rescuer will be prompted to continue chest compressions and there will be no pause for rhythm analysis. Occasionally, cprINSIGHT will reach no decision, which means that the analysis is inconclusive. The rescuer will then be prompted to stop chest compressions to allow SAS to perform an analysis. This is a safety feature designed to provide an additional analysis in these occasional situations.

The illustration on the following page shows how cprINSIGHT analysis technology can shorten pre-shock pauses during CPR. In the shock advised scenario, 10 seconds of pause in CPR is eliminated. In the no shock advised scenario, 14 seconds of pause in CPR is eliminated. In the event no decision is reached, the pause duration will be the same as it is with a conventional AED.

How does cprINSIGHT analysis technology improve resuscitation efforts?

Pauses in chest compressions during a resuscitation event can be detrimental to survival. Not only do pauses drastically reduce circulation to the heart, but blood flow to the brain is also dramatically reduced. The AHA currently recommends keeping pauses in chest compressions to 10 seconds or less. Chest compression fraction (CCF) is the percentage of time during a resuscitation event spent doing chest compressions. AHA recommends CCF of at least 60 percent.



*Note: These prompts are delivered during the first analysis after defibrillation pads are placed to obtain a baseline decision without compression artifact.

Accuracy and CPR improvement

The LIFEPAK CR2 AED with cprINSIGHT analysis technology was compared with a conventional device (LIFEPAK 1000 AED) by first responders (police and firefighters). Both algorithm accuracy and CPR performance improvement were reported. 6

- Accuracy cprINSIGHT reached a treatment decision (S or NS) during chest compressions 70 percent of the time. cprINSIGHT correctly identified shockable rhythms during chest compressions 95.5 percent of the time and nonshockable rhythms 98.2 percent of the time.
- Improvements in CPR performance CPR pauses before a shock, also referred to as pre-shock pauses, were drastically reduced to an average of eight seconds vs. an average of 22 seconds with the conventional AED. Chest compression fraction with cprINSIGHT was 86 percent vs. 80 percent in the conventional AED group.

Conclusion

cprINSIGHT analysis technology was designed to reduce pauses in chest compressions and increase hands-on time during the treatment of SCA victims with the LIFEPAK CR2 and is safe and effective for use on adults and children. cprINSIGHT analysis technology on the LIFEPAK CR2 is highly effective in increasing CPR time and reducing pauses in CPR. Such improvements in CPR have been shown to be associated with better outcomes for victims of SCA.^{5,7}

LIFEPAK CR2 defibrillator

BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE:

LIFEPAK CR2 AED is indicated for use on patients 1 year of age or older in cardiopulmonary arrest. The patient must be unresponsive (unconscious), not breathing normally, and showing no signs of circulation (for example, no pulse, no coughing, or no movement). cprCOACH TM Feedback Technology in CR2 AED is indicated for use on cardiopulmonary arrest patients and provides CPR guidance in accordance with AHA Guidelines for patients 1 year of age or older. AED is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support/AED, advanced life support, or a physician-authorized emergency medical response training program. The LIFEPAK CR2 Defibrillator is indicated to be used with the OUIK-STEP TM Pacing/ECG Defibrillation Electrodes and the LIFEPAK CR2 Lithium Battery.

CONTRAINDICATIONS:

LIFEPAK CR2 AED is not indicated for patients who are conscious and responsive.

DANGER:

Do not use LIFEPAK CR2 in presence of flammable gases or anesthetics.

WARNINGS:

- LIFEPAK CR2 AED delivers up to 360 joules of electrical energy. Unless used properly by following AED's visual and audio prompts, this electrical energy may cause serious injury or death.
- When instructed EVERYONE CLEAR, do not touch AED, patient, electrode pads
 or any material/fluid in contact with patient. Make sure no one is touching patient
 when AED shocks patient.
- Do not immerse AED in water or other fluids. Avoid spilling fluids on AED or its accessories.
- Do not store in presence of flammable gases, anesthetics or in direct contact with flammable material. Use care when operating close to oxygen sources. Turn off gas source or move it away from patient during defibrillation.
- Equipment operating in close proximity may emit strong electromagnetic interference (EMI) or radio frequency interference (RFI) which could affect performance of AED.
- Keep AED away from magnetic resonance imaging (MRI) equipment as it is unsafe.
- AED should not be used adjacent to or stacked with other equipment.
- · Do not touch patient and USB connector on back of AED simultaneously.
- Replace battery immediately when AED indicates battery is low.
- Use only accessories specified by Stryker. Using other manufacturers' accessories may cause AED to perform improperly and may invalidate safety agency certification. Contact authorized service personnelfor repair.

- · QUIK-STEP electrode pads: Place pads so they adhere to skin completely.
- · Do not allow pads to touch each other or any material on patient's chest.
- Do not use damaged, expired, or dried-out pads. Dried out or damaged pads may cause electrical arcing and skin burns during defibrillation.
- · Do not pull red handle to open electrodes until immediately before use.
- QUIK-STEP electrodes provided with CR2 are not compatible with LIFEPAK 500 device. Emergency medical personnel should not connect these electrodes to LIFEPAK 500 device.

CAUTIONS:

- Damaged batteries may leak and cause personal injury or equipment damage; handle with extreme care.
- Do not open device lid unnecessarily as this will reduce internal battery power.

POTENTIAL ADVERSE EFFECTS (for example, complications):

- · Failure to identify shockable arrhythmia
- Failure to deliver a defibrillation shock in presence of ventricular fibrillation (VF) or pulseless ventricular tachycardia, which may result in death or permanent injury
- Inappropriate energy delivery which could cause failed defibrillation or postshock dysfunction
- · Myocardial damage
- · Incorrectly shocking a pulse-sustaining rhythm and inducing VF or cardiac arrest
- Bystander shock from patient contact during defibrillation shock
- · Interaction with pacemakers
- Skin burns around electrode pad placement area
- Allergic dermatitis due to sensitivity to materials used in electrode construction $\,$
- Minor skin rash
- Fire hazard in presence of high oxygen concentration or flammable anesthetic agents
- EMI from AED impacting other devices especially during charge and energy transfers

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

Please consult Operating Instructions at www.strykeremergencycare.com or call 800.442.1142 for complete list of indications, contraindications, warnings, cautions, potential adverse events, safety and effectiveness data, instructions for use and other important information.

References

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For further information, please contact Stryker at 800 442 1142 (U.S.), 800 668 8323 (Canada) or visit our website at strykeremergencycare.com

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